55th IPC 2003

CHENNAI

55th Indian Pharmaceutical Congress 2003

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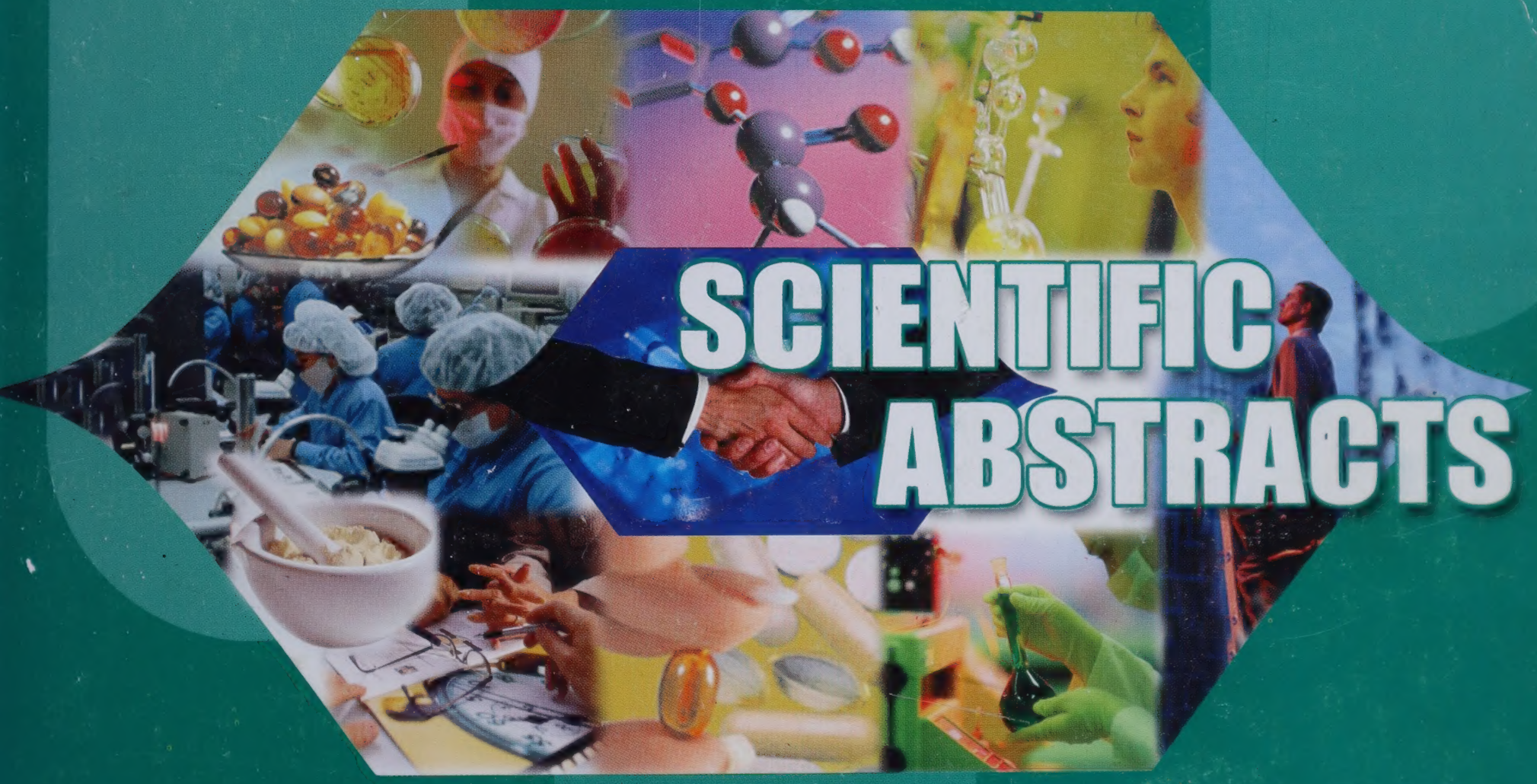
The Indian Pharmaceutical Association
Tamil Nadu Branch & 55th IPC - LOC



SCIENTIFIC ABSTRACTS

Theme : Pharmacy, Medicine Management and the National Health Policy

December 19, 20, 21 - 2003

Venue

Sri Ramachandra Medical College & Research Institute
Deemed University, Porur, Chennai

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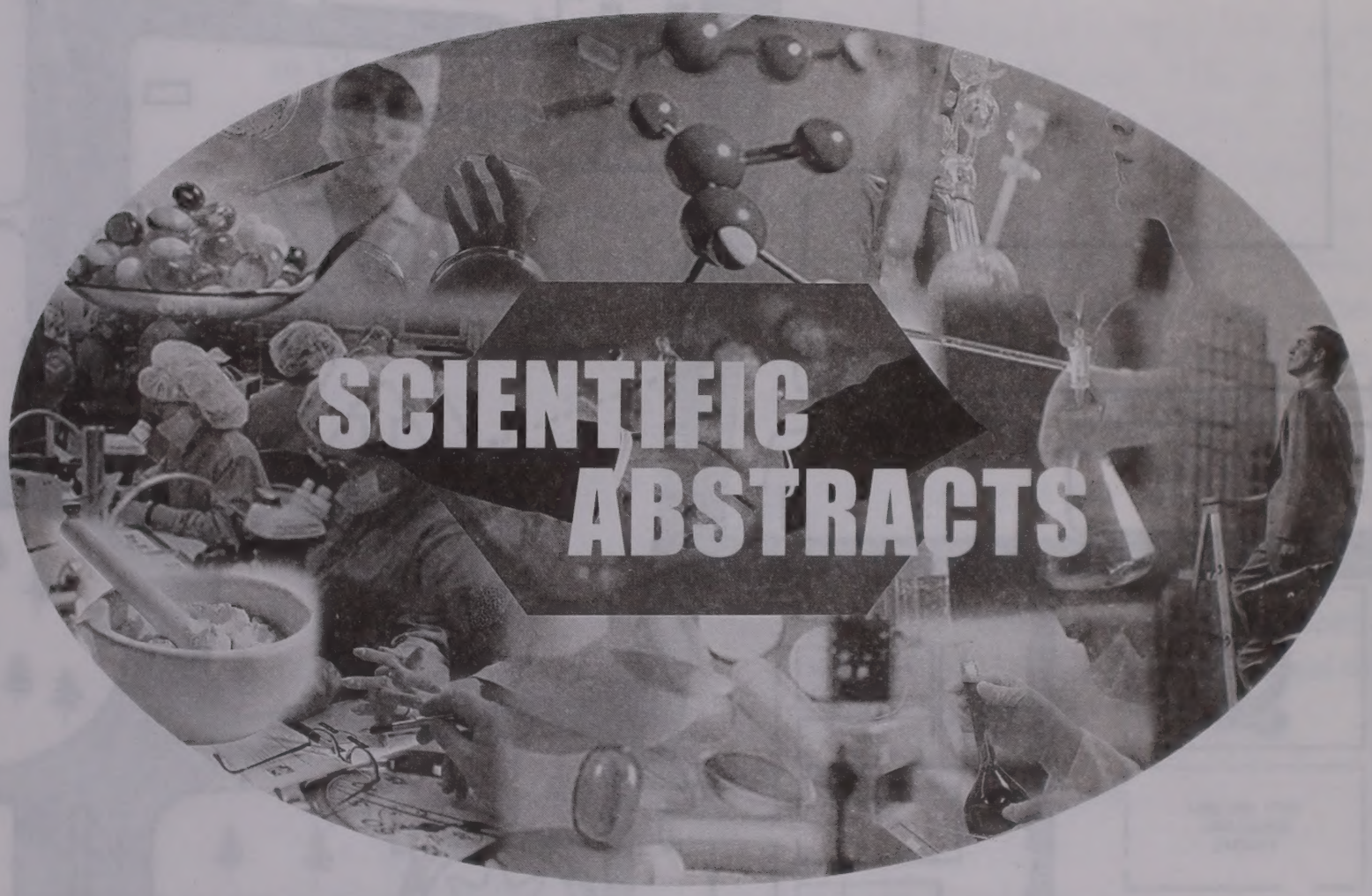
55th IPC 2003

CHENNAI

55th Indian Pharmaceutical Congress 2003



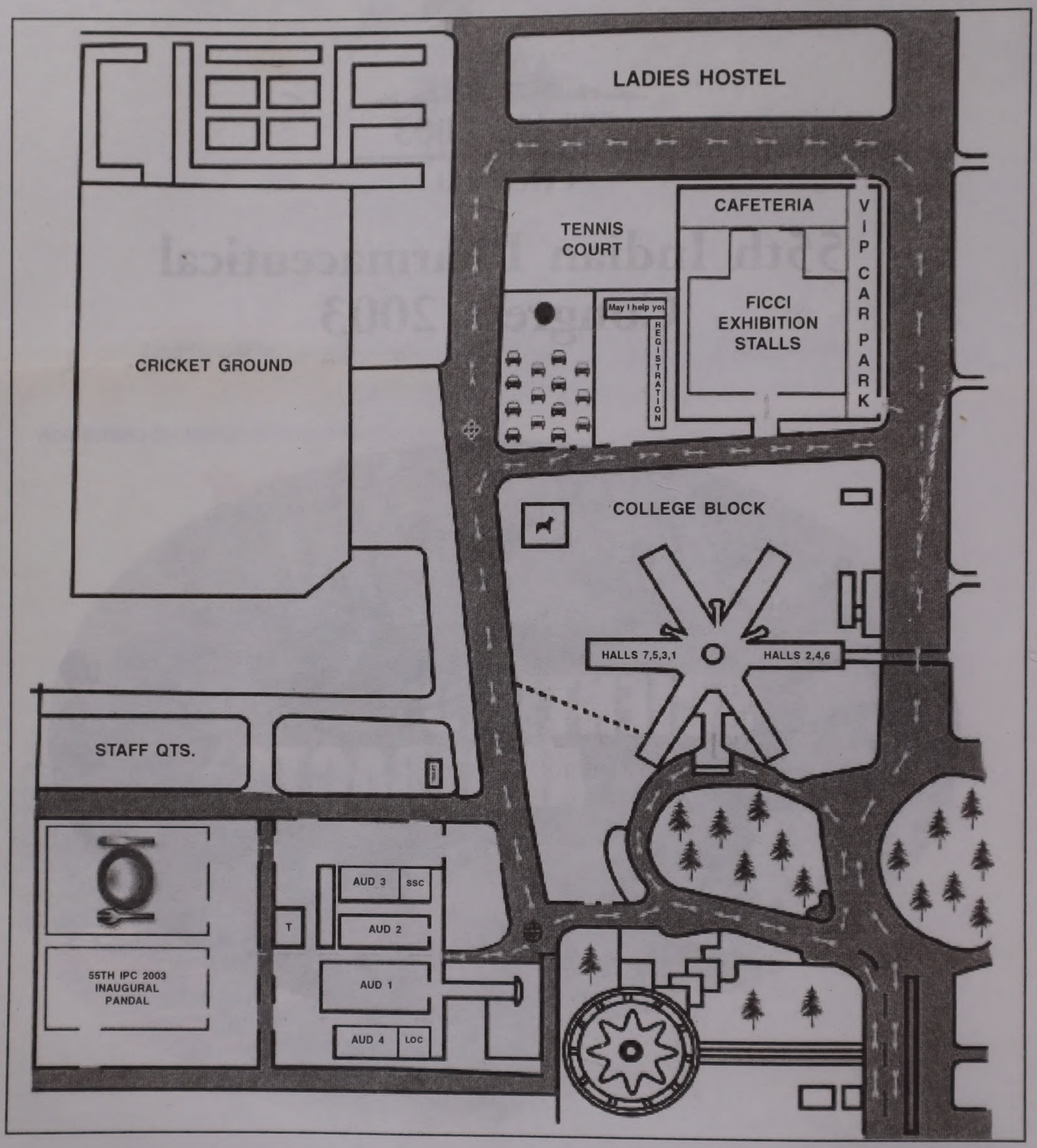
THEME : PHARMACY, MEDICINE MANAGEMENT AND THE NATIONAL HEALTH POLICY

December 19, 20 & 21 - 2003

Venue

Sri Ramachandra Medical College & Research Institute
Deemed University, Porur, Chennai

CONFERENCE MAP



MAIN ENTRANCE

Auditorium 1	-	*Theme Sessions*
Auditorium 2	-	*Research & Development / Education Sessions*
Auditorium 3	-	*Pharmacy Practice Sessions*
Auditorium 4	-	*Scientific Poster Sessions*
Inaugural Pandal (Main Pandal)	-	*Panel discussions & Entertainment*
SSC	-	*Scientific Services Office / Preview Hall for speakers*
LOC	-	*LOC Office / VIP Lounge*

Hall 1 (Ground Floor)	-	*Preview Hall*
Hall 2 (First Floor)	-	*Scientific Oral Presentation*
Hall 3 (First Floor)	-	"
Hall 4 (Second Floor)	-	"
Hall 5 (Second Floor)	-	"
Hall 6 (Third Floor)	-	"
Hall 7 (Third Floor)	-	"

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Message

It is with pleasure I see that the 55th Indian Pharmaceutical Congress being organized at Chennai from December 19 to 21, 2003 is not only going to be an event for pharmacy professionals together, but also an event which is going to bring a confluence of scientists disseminating latest developments in the pharmaceutical sciences at the various symposia and plenary lectures organized as a part of the Congress. I am also glad to note that there was a large interest amongst young scientific community to make presentations, both in the oral and poster sessions of the Congress thereby indicating the quantum of research activities taking place in our country. However, to maintain the quality as well as to achieve the objectives of the Congress within the framework of time available to us, we had to limit the same to 900 presentations, which I am given to understand, is the largest number till date being presented at the Indian Pharmaceutical Congress since the past 54 years.

I congratulate the Scientific Convener and his Committee as well as the Scientific Committee of the Local Organizing Committee for putting up a meaningful and useful scientific programme for the benefit to delegates attending the Congress.

I wish the Congress and Scientific Programmes a grand success.

SRI. ASHWINI KUMAR
PRESIDENT
55th IPCA, CHENNAI

Message

Indian Pharmaceutical Congress is known for its magnanimity and versatility. Looking in to the number of delegates and diversity in the topics generally deliberated, there could be hardly any such scientific event in the country, except Indian Science Congress, which is celebrated in such a scale and also to meet many objectives. In addition to scientific deliberations, exhibition and official meetings, IPC facilitates many number of activities like revival of friendship, alumni activity, sales promotion and even search for talents in the field of Pharmacy. This three day event takes delegates to their student days not only with respect to lectures on diversified discipline of science and Pharmacy, but also in spending some happy moments with their classmates, old colleagues, friends and provides opportunity to make new friends and new contacts.

"Pharmacy, Medicine Management and National Health Policy" - is a well defined theme for this IPC in a situation when the Indian pharmacists are trying hard to get themselves identified as a true professional and make a place in the health care program of the country. While the rest of the world looks towards pharmacists for proper advise on drugs, counselling for proper use of medicine and as a friendly professional, the image of the Indian pharmacist has not gone beyond the perception of a trader standing behind the counter of a medical shop (Even often called as a drug store) and selling medicines. The situation may be due to socio-economic problems, lack of knowledge on drugs in a Indian Registered pharmacist (Minimum education requirement for registration in India being Diploma in Pharmacy, while in most of the other countries is a degree in Pharmacy or even higher than this). It is high time that the Indian pharmacist should come out of the 'trade brand' to a 'professional brand' and should take a direction where the public can identify him as a professional with responsibility of safe guarding public health.

Quite a good percentage of expenditure of the health care is spent on drugs. Though the cost of medicine in India is very low in comparison to the rest of the world, the per-capita income of majority of Indian population cannot simply afford. Such a commodity should be properly managed to avoid wastage, loss of potency and with care to avoid toxicity and adverse reactions. Medicines management is a guide line for judicious and rational selection of drugs with well defined storage methods and meticulous distribution system without misuse. Particularly for controlled drugs, effective medicine management can only ensure proper usage without being letting it in wrong hands.

Advent of biotechnology and biotechnological drugs posed new challenges to pharmacists for their proper usage and preservation. This needs proper education and responsibility for its formulation, manufacturing, preservation distribution and usage. The most important element in meeting this challenge is the rationalization of Pharmacy education to produce human resource. This congress would focus these key issues in addition to highlighting advancements made in industrial pharmacy, drugs discovery and delivery system development.

The symposiums, plenary lectures and other sessions scheduled in this congress would deliberate on issues like Rational Use of Drugs, Pharmacovigilance, Medicine management, National Health Policy etc. for which experts from India and abroad are invited. In total, 30 sessions are programmed out of which there are 15 symposiums, 8 plenary lectures, 3 memorial lectures and 3 panel discussions. About 7 sessions are devoted for discussion on various aspects of the theme of the Congress. Other sessions deliberate issues on education, Clinical Pharmacy, formulation and manufacture, drug development and regulatory aspects. In total 80 experts are invited to participate in various sessions out of which 40 are from various countries outside India like USA, UK, Australia, Germany, Japan, Philippians, Hong Kong, Singapore South Africa, Malasiya and UAE.

The response for research paper presentation in various sessions is extremely good. Including quite a few of foreign papers, the total number of entries this year is all time record of 2100. A foolproof method of evaluation was adopted to screen these papers and to select 360 papers for oral presentation magnitude has certainly made the work of the scientific committee very tough but the committee is very happy that, the process appreciably increased the overall standard of papers that are selected for presentation. A foolproof mechanism has also been worked out to select best paper presented in oral and poster sessions of individual sections.

This Herculean task of arranging scientific in this scale is an out come of hard work put up by the members of the scientific services committee and untiring service rendered by the P.G. Students and research scholars of the pharmacy department, M.S. University of Baroda for whom I am really grateful. I also thank IPCA committee, Chairman and Members of the Scientific Committee (LOC), Organising secretary and other members of the LOC for their overwhelming support, advise and assistance to make this task possible.

PROF. R.S.R. MURTHY
CONVENER
SCIENTIFIC SERVICES COMMITTEE
55th IPC, CHENNAI

Message

Scientific Programme of the 55th IPC at the capital city of Tamil Nadu, Chennai, has been carefully drafted so that scientific deliberations would have a remarkable impact on the health policy of India. The Congress would also be highlighting the importance of Pharmacy Profession in efficient drug management for better healthcare of the society. Apart from the theme session, there are 3 Memorial Lectures, 3 Panel Discussions, 14 Symposia, 9 Plenary Lectures which encompass all the relevant areas on drug discovery, clinical research, herbal standardization and pharmaceutical technology.

The response to the oral and poster sessions have been overwhelming, indicating the enthusiasm of the pharmacy fraternity. The interaction of the Eminent Speakers, Chairmen and Delegates would be of great benefit for the development of our profession. I am sure that the scientific abstracts would help to initiate new dimensions of pharmaceutical research catering to the needs and challenges ahead in the next decade. Any shortcomings in this scientific abstract, may be magnanimously overseen at this juncture, though if brought to our notice, would help us improve and aim for near perfection in our next venture.

"Think Globally Act Locally"

DR. T.K. RAVI
CHAIRMAN
SCIENTIFIC SERVICES COMMITTEE (LOC)
55th IPC, CHENNAI

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55th Indian Pharmaceutical Congress, Chennai

19th - 21st December 2003

Scientific Programme

DECEMBER 19th 2003 9.00 AM TO 12.00 NOON INAUGURAL FUNCTION MAIN PANDAL

Auditorium 1 (Theme Sessions)

14.15	**Symposium 1 : Presidents Symposium** **Theme** : **Pharmacy, Medicine Management and National Health Policy** **Speaker 1** : **Dr. M.D.Nair**, Pharmaceutical Consultant, Chennai **Topic** : National Health Policy **Speaker 2** : **Dr. Malcolm Patridge**, Chief Pharmacist Queen's Medical Center, Nottingham University, Nottingham, UK **Topic** : Medicine Management - An Insurance policy for safe practice **Speaker 3** : **Dr. Ruth Fergusson**, New Zealand **Topic** : Drug Safety Monitoring – A global perspective	**Chairman :** Sri Ashwini Kumar, President, 55th IPC, Chennai **Co-Chairman :** Prof.K.Chinnaswamy, Hon. General Secretary, IPCA
16.15	Tea Break	
16.30	**Shri B.V.Patel Memorial Lecture** **Speaker** : **Mr. P.D.Sheth**, President, Indian Pharmaceutical Association, Mumbai **Topic** : Globalization of Indian Pharmacist- Where we are? Where we should be going?	**Chairman** : Sri.S.P.Adeshara, Chairman, Shri B.V.Patel Education Trust, Ahmedabad **Co Chairman** : Mr.Anil Kumar, Pharmacist, Ministry of Health, Abu Dhabi, UAE

Auditorium 2 (Research and development/education)

14.15	**Symposium 2 : Drug Discovery** **Speaker 1** : **Dr.S.K.Agarwal**, Orchid Chemicals and Pharmaceuticals, Chennai **Topic** : Recent developments in Antibacterial Oxazolidinones **Speaker 2** : **Dr.S.B.Katti**, CDRI, Lucknow **Topic** : Identification and characterization of diagnostically relevant major epitope of A.fumigatus. **Speaker 3** : **Dr.S.P.Gupta**, Department of Chemistry, BITS, Pilani, Rajasthan **Topic** : Rational approaches to Drug Discovery **Speaker 4** : **Dr.R.K.Sharma**, INMAS, Delhi **Topic** : Nuclear Medicine Imaging- A development tool in pharmaceutical research	**Chairman :** Dr.V.S.V.Vadalmudi Rao, Suven Pharmaceuticals, Hyderabad **Co-Chairmen :** Dr. M.N.A.Rao, Divi's Laboratories, Hyderabad Dr.Jayashekar, College of Pharmaceutical Sciences, Trivandrum
16.15	Tea Break	
16.30	**Plenary Lecture 1** **Speaker** : **Prof.Paul Heng**, The National University of Singapore GEA-NUS Pharm. Processing Research Lab., Dept. of Pharmacy, Singapore **Topic** : Special Techniques in formulation design and quality control	**Chairman :** Mr.R.Thiruvengadam, Director. Tablets India Ltd., Chennai **Co-Chairman :** Dr.Y.Madhusudan Rao, Dean, Kakatiya University, Warangal
17.30	**APTI Meeting**	

Auditorium 3 (Pharmacy Practice Sessions)

14.15	**Symposium 3 : Rational Use of Drugs** **Speaker 1** : **Ms.Karin Nyfort Hansen**, Senior Clinical Pharmacist, Repatriation General Hospital, Daws Park, South Australia **Topic** : Rational Drug Use and Evidence based medicine **Speaker 2** : **Prof.C.J.Shishoo**, Consumer Education and Research Society, Ahmedabad **Topic** : RUD- Monitoring adverse drug reactions **Speaker 3** : **Mr.George K.John**, Potchefstroom University, South Africa **Topic** : Pharmacy in South Africa: An Overview	**Chairman :** Dr Shrotriya, Ahmedabad **Co-Chairman :** Dr.G.Parthasarathi, JSS College of Pharmacy, Mysore
16.15	Tea Break	
16.30	**Plenary Lecture 2** **Speaker** : **Mr. David Cosh**, Netherby, South Australia **Topic** : Accreditation of Clinical pharmacy practitioners for community practice- Attaining and maintaining competence	**Chairman :** S.L.Nasa, New Delhi **Co-Chairman :** Dr.Gurbani, Jaipur

Hall 7 AIDCOC Meeting - Time : 14.30 onwards

MAIN PANDAL - ENTERTAINMENT PROGRAMME - TIME : 18.30

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DECEMBER 20th 2003 - Auditorium 1 (Theme Sessions)

09.00	**Prof.M.L.Khorana Memorial Lecture :** **Speaker** : **Prof.C.K.Kokate**, Vice Chancellor, Kakatiya University,Warangal **Topic** : Value crisis in higher education - causes and remedies	**Chairman** : Mr. P.D. Sheth President IPA, Mumbai **Co-Chairman** : Prof.M.D. Karvekar Member Secretary, Board of Examination, Bangalore
10.00	**Plenary Lecture 3 :** **Speaker** : **Mr.Subodh Priolkar**, Director, Valois (I) Ltd., Mumbai **Topic** : **Post GATT Implications in NHP**	**Chairman** : Prof.H.L. Bhalla, SciTech Centre, Mumbai. **Co-Chairman** : Prof. K.N. Gujjar, Singhad College of Pharmacy,Pune
11.00	Tea Break	
11.15	**Symposium 6** : **Regulatory issues with respect to NDA and ANDA** **Speaker 1** : **Mr.Vivek Kapur**, Group Leader, International Drug Regulatory Affairs, Ranbaxy Laboratories Ltd., SAS Nagar, Mohali **Topic** : Post Approval changes to DMF, ANDA & MAAs in US & EU, and change control management **Speaker 2** : **Dr.U.V.Banakar**, Banakar Consulting Services, 10251, Carmel, USA **Topic** : Pre formulation parameter requirements, NDA & ANDA **Speaker 3** : **Mr.S.W.Deshpande**, Secretary General, AIDCOC, Mumbai **Topic** : Regulatory issues with respect to ANDA **Speaker 4** : **Dr.D.A.Limaye**, Head, Drug Regulatory Affairs,Aventis Pharma, Mumbai **Topic** : Top floor to shop floor : In Pharmaceutical Industry	**Chairman** : Mr.C.Gopalkrishnamurthy, Retd. Drug Controller, Hyderabad **Co-Chairmen** : Prof.S.C.Chaturvedi, Vice Chancellor, Rajiv Gandhi Technical University, Bhopal Dr. Easa Ahmed Al Mansoori, Director, Drugs Control Department, UAE.
13.15	Lunch	
14.15	**Symposium 9** : **Pharma-Industry: Issues and new opportunities** **Speaker 1** : **Dr. Raghavendra Rao**, Orchid Health Care Ltd., Chennai **Topic** : New opportunities for Pharma industry **Speaker 2** : **Mr.B.G.Kini**, Mumbai **Topic** : Process validation - Pharma & Bulk products **Speaker 3** : **Mr.Sachin Itkar**, Consultant, Pune. **Topic** : Export potential of NDDS-A growth perspective for Indian Pharma Industries **Speaker 4** : **Dr.Venkat Jasti**, Suven Pharmaceuticals, Hyderabad **Topic** : GMP update	**Chairman** : Mr.Pankej Patel, Cadila Laboratories, Ahmedabad **Co-Chairmen** : Dr.D.R.Patel, Astral Pharmaceuticals, Vadodara
16.15	Tea Break	
16.30	**Symposium 9 (continued)** **Speaker 5** : **Dr.D.B.A.Narayana**, HLL Research Center, Mumbai **Topic** : Need for good storage practice specifically for India **Speaker 6** : **Mr.Atul Shirgaonker**, Insight systems, Pune **Topic** : Facing International GMP audit successfully	Dr.Harish Padh, Director, B.V.Patel PERD Centre,Ahmedabad
17.30	**Plenary Lecture 4A** **Speaker 1** : **Dr.Ramagopal V.Mudumbi**, Associate Director, Cardiovascular and Urology division, GlaxoSmithkline, USA **Topic** : Issues and challenges in Drug Discovery & Development	**Chairman** : Dr. Venkatramanan, Dean, AL-PGIBMS, Taramani, Chennai. **Co-Chairman** : Dr.C.V.Subramaniam Principal, Bapuji College of Pharmacy, Davanakare
17.30	**PCI Inspectors Meeting**	Harvard Hall
18.15	**IPA - AGM**	

Auditorium 2 (Research and development/education)

09.00	**Symposium 4** : **Nano Particle Technology - Super critical fluid technology** **Speaker 1** : **Prof.Kompella**, Department of Pharmaceutical Sciences, Nebraska Medical Center, Omeha, USA **Topic** : Supercritical fluid technology for respiratory Drug Delivery systems **Speaker 2** : **Prof B. Pitchumani**, Particle Size & Tech. Laboratory, IT, Delhi **Topic** : Application of particle technology in Pharma Industry **Speaker 3** : **Dr.Ram B.Gupta**, Dept. of Chemical Engg, Auburn University Auburn **Topic** : Formation of Drug Nanoparticles and Microparticles using Supercritical Fluids	**Chairman** : Dr.Amarjeet Singh, Sun Pharma Ind. Ltd, Mumbai **Co-Chairmen** : Prof.N.Udupa, College of Pharmaceutical Sciences, Manipal Dr. B K Sahoo, AICTE New Delhi
11.00	Tea Break	
11.15	**Symposium 7** : **Special techniques in Drug Delivery Technology** **Speaker 1** : **Dr. Moses Chow**, Faculty of Medicine, The Chinese University of Hong Kong, Shatin NT, Hong Kong **Topic** : Continuous cell-line-New screening model for oral mucosal drugdelivery **Speaker 2** : **Prof.N.K.Jain**, Dr.H.S.Gaur Viswavidyalay, Sagar **Topic** : Special delivery strategies in Helicobactor pylori treatment **Speaker 3** : **Prof.S.Ramakumar**, Chairman, Bio-informatics Center, IISC Bangalore **Topic** : Bio-informatics in the post genomic era **Speaker 4** : **Mr.Arun Ramanathan**,Secretary to Govt. of Tamilnadu **Topic** : Ticel Biopark-TamilNadu Government's Gateway for Medical Biotechnology	**Chairman** : Dr.Sushil Khanna, Ranbaxy Laboratories, Mohali **Co-Chairmen**: Prof.S.G.Deshpande, Mumbai Prof.K.Kannan, Dean, School of Bio-Technology, Guru Gobind Singh, Indra Prastha University, New Delhi.
13.15	Lunch	
14.15	**Symposium 10** : **Advanced techniques in Herbal drug standardization** **Speaker 1** : **Dr.M.J.Nanjan**, Director, TIFAC CORE in Herbal Drugs, Ooty **Topic** : TIFAC CORE in herbal drugs- A step towards need based education **Speaker 2** : **Dr.(Mrs.)Shanta Mehrotra**, NBRI, Lucknow **Topic** : Quality evaluation of Herbal Drugs - A present day need **Speaker 3** : **Dr.M.K.Raina**, Consultant, Ayurvedic & Herbal Medicines, Mumbai **Topic** : Role of biological assays in the standardization of herbal drugs **Speaker 4** : **Mr.M.F. Farooqui**, I.A.S., Commissioner of Indian Medicine & Homeopathy, Chennai	**Chairman** : Dr.K.A.Narenderanath, TTK Pharma, Chennai **Co-Chairmen**: Prof.S.H.Mishra, MS University of Baroda, Vadodara Dr Hukkeri, KLE's College of Pharmacy, Hubli
16.15	Tea Break	**Chairman** : Dr.G. Ramakrishnan Vice President, Agilant Technology, New Delhi **Co-Chairman**: Mr.Sathyanarayana, SIPRA Laboratories, Hyderabad
16.30	**Plenary Lecture : 4** **Speaker** : **Dr. Ludwig Huber**, Agilant Technologies, Germany **Topic** : Latest developments on US FDA and EU guidelines for Pharma Industries	
17.30	**Podium Presentation and Discussion** Opportunities for industrial tie-up and collaborative research in Pharma sector: TIFAC Centers of relevance and excellence (CORE), a viable role model **1. TIFAC CORE in Herbal Drugs, JSS College of Pharmacy, Ooty** **2. TIFAC CORE in NDDS,Pharmacy Department,M.S.University of Baroda,Baroda** **3. TIFAC CORE in Biotechnology, Thaper Institute, Patiala**	**Co-ordinators** : Dr. M.S. Vijaya Raghavan, DRDO, Bangalore Dr. Deepak Bhatnagar, Advisor, TIFAC, Govt. of India, New Delhi
18.30	**IHPA Meeting**	

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DECEMBER 20th 2003 - Auditorium 3 (Pharmacy Practice Sessions)

09.00	**Symposium 5 : Pharmaco-epidemiology and health policy** **Speaker 1** : **Dr.Tom Elnerson**, Associate Professor, Faculty of Pharmacy and University of Toronto, Canada **Topic** : Pharmaco-epidemiology and health policy- Issues for India **Speaker 2** : **Dr.S.J.Chandy**, Dept. of Pharmacology, CMC, Vellore **Topic** : Pharmaco-epidemiology and the Pharmacist **Speaker 3** : **Dr.Bruno Louis**, Senior, . Clinical Pharmacist, SQ University Hospital, Muscat. **Topic** : Drug utilization studies using ATC/DDD methodology	**Chairman** : Dr.Prem K.Gupta, New Delhi **Co-Chairmen**: Dr.Laxman Prasad Department of Science & Technology, New Delhi Prof.S.D.Rajendran, JSS College of Pharmacy, Ooty
11.00	Tea Break	
11.15	**Symposium 8 : Alzheimer's disease and it's management** **Speaker 1** : **Dr.Stefan Kawolski**, University of South Australia **Topic** : Drug treatment of Alzheimer's disease:Global and individual perspective **Speaker 2** : **Prof.S.K.Kulkarni**, UCPS, Chandigarh **Topic** : Memory enhancing and Anti-amnesic Agents from Natural Source	**Chairman** : Dr.C.L.Kaul NIPER, Mohali **Co-Chairman** : Dr. Khanijo, Drugs Controller Administration, New Delhi
12.30	**Plenary Lecture : 3A** **Speaker** : **Mr.Praful Naik**, Bilcare, Pune **Topic** : Trends in Packaging technology	**Chairman** : Prof B G Shivananda, Al-Ameen College of Pharmacy, Bangalore **Co-Chairman** : M.M. Yousuf, Drugs Control Dept., Chennai
13.15	Lunch	
14.15	**Symposium 11 : Clinical Pharmacokinetics - Where we are?** **Speaker 1** : **Mr.Iqbal Ramzan**,Associate Professor,University of Sydney,Australia **Topic** : Neuromuscular blockers as potential Pharmacokinetic / Pharmaco-dynamic probes of graft function during liver transplantation. **Speaker 2** : **Prof.D.R.Krishna**, Kakatiya university, Warangal **Topic** : Therapeutic drug monitoring Vs Target concentration intervention: Which is the right strategy in individualization of drug therapy? **Speaker 3** : **Dr.S.Jambhekar**, Professor and Head, Industrial Pharmacy Department, Massachusetts College of Pharmacy, USA **Topic** : Principles of multiple dosing pharmacokinetics	**Chairman** : Dr. M.C. Prabhakar, Kakatiya University, Warangal **Co-Chairman:** Dr. P.V. Diwan, IICT, Hyderabad
16.15	Tea Break	
16.30	**Plenary lecture: 5** **Speaker** : **Prof.P.C.Dandiya**, WHO Consultant in Community Pharmacy, Jaipur **Topic** : A WHO sponsored survey of the present status of community pharmacist in Rajasthan	**Chairman** : Mr. Mohan Bazaz, New Delhi **Co-Chairman** : Mr. A.Krishna Dev, Chennai
17.30	**Plenary lecture 5 A** **Speaker** : **Mr.Richard W.Streamer**, Technical Manager,FOSS NIR Systems,USA **Topic** : Implementing NIR Methods for Raw-material Inspection	**Chairman**: Mr. Parthajyothi Gogoi, Regional Drugs Testing Laboratory, Guwahati, **Co-Chairman**: Mr.Sengupta, Ghaziabad
18.15	**IPGA Meeting**	

Main Pandal (Panel Discussion)

09.00	**Panel Discussion 1 :** **Community Pharmacy in India- Only a buzz word or a future reality** **Speaker 1** : **Mr.J.Shinde**, President, AIOCD, Mumbai **Topic** : Community pharmacy in India - Prospects and perspectives **Speaker 2** : **Mr John Bell**, President, Commonwealth Pharmaceutical Association, Australia **Topic** : Self Care – A programme to Provide Both professional and Financial rewards for Community Pharmacy **Speaker 3** : **Dr.S.R.Sarvadekar**, Chief Pharmacist, Medical Store J.J. Hospital, Mumbai	**Chairman :** Mr.B.R.Shetty, CMD, NMC Group, Abu Dhabi, UAE **Co-Chairmen :** Mr.D.Gundu Rao, President Karnataka C&D Association. Mr. A R Singh, Drugs Control Department, Chennai
11.00	Tea Break	
11.15	**Panel Discussion continues** **Speaker 4** : **Mr.Batu Andrade**, Joint Secretary (West Zone), AIOCD, Mumbai **Speaker 5** : **Mr.R.Srinivasan**, AIOCD, Chennai **Topic** : Community Pharmacy in India - A Practical Approach **Speaker 6** : **Mr.T.Ilango**, Registrar, Tamil Nadu Pharmacy Council Chennai **Topic** : Responsibility of Pharmacist as per Pharmacy Act	
13.15	Lunch	
14.15	**Panel Discussion 2 :** **Pharmaceutical Education in India- Current scenario and future direction (program by Shri. B.V Patel Education Trust, Ahmedabad)** **Panel Members :** 1. **Mr.P.D.Sheth**, President,Indian Pharmaceutical Association, Mumbai 2. **Prof.Motoko Kanke**, Kyoritsu, College of Pharmacy, Tokyo, Japan 3. **Prof.R.S.R Murthy**, M.S.University of Baroda, Vadodara 4. **Dr.R.S.Gaud**, Advisor, AICTE, New Delhi	**Panel Co-ordinators:** Dr.S.P.Adeshara, Commissioner, FDCA, Gujarat state Prof Vimaladevi, Pondicherry Mr.Prabashanker, President, KUPPAH and student coordinator IPA Education Division
16.15	Tea Break	
16.30	**Panel discussion continues** 5. **Dr.Sindchai**, Asian Association of Schools of Pharmacy, Thailand 6. **Prof.Mrs.Nagarsenkar**, Bombay College of Pharmacy, Mumbai	
18.30	**ENTERTAINMENT**	

55th Indian Pharmaceutical Congress, Chennai

DECEMBER 21st 2003 - Auditorium 1 (Theme Sessions)

09.00	**Shri K.C.Chatterjee Memorial Lecture** **Speaker** : **Dr.P.Bindra**, Vice President, Ranbaxy Laboratories, New Delhi **Topic** : World Class Manufacture	**Chairman** : Mr.P.P.Sharma, President, IPGA, New Delhi **Co Chairman** : Atul K Nasa, Secretary, IPGA, New Delhi
10.00	**Plenary Lecture : 6** **Speaker** : **Dr.Gowri Chaudhury**, Strategic Consultant, FCB Ulka Advertising Ltd., Mumbai **Topic** : Rescripting Pharma Marketing in Post patent era	**Chairman** : Prof.R.K.Khar, Jamia Hamdard, New Delhi **Co-Chairman** : Dr. Burande, Poona College of Pharmacy, Pune
11.00	Tea Break	
11.15	**Symposium** : **14 Clinical research- emerging opportunities for pharmacists** **Speaker 1** : **Mr.Brijesh Regal**, Apothecaries Limited, New Delhi **Speaker 2** : **Dr.Adeep Bagati**, Cadila Pharma Ltd., Ahmedabad **Topic** : Clinical research - an emerging opportunity for pharmacist **Speaker 3** : **Dr.M.Vasudevan**, Director, CADRAT, JSS College of Pharmacy,Ooty. **Topic** : Perspective and oppurtunities in clinical Pharmaco Kinetics	**Chairman** : Sri.Ashwini Kumar, President, 55th IPC, Chennai **Co-Chairmen:** Prof.V.B.Desai, Advisor, JSS College of Pharmacy, Ooty Mr.M.Kannan, Deputy Director, Drugs Control Dept, Chennai
13.15	Lunch	
14.15	**OPEN SESSION**	
15.30	**VALEDICTORY PROGRAMME**	

Auditorium 3 (Pharmacy Practice Sessions)

09.00	**Symposium 13: Medicine Management, Pharmacovigilance and Drug Distribution** **Speaker 1** : **Dr.Venkateshwaralu,** Deputy. Drugs Controller (I) C.D.S.C.O.West Zone, Mumbai **Topic** : Medicine Management- regulatory perspective **Speaker 2** : **Mr.Atul Shirgaonker,** Insight systems, Pune **Topic** : European guidelines: Good Drug Distribution Practice	**Chairman:** Mr.Sher Singh Thakur, Drugs Controller, Simla **Co-Chairmen:** Mr.Deenadayalan, Food & Drugs Administration, Pondicherry Mrs.Archna Mudgal, Secretary, Pharmacy Council of India, New Delhi
11.00	Tea Break	
11.15	**Plenary Lecture 7** **Speaker** : **Dr.V.P.Shah**, US FDA, Washington, USA **Topic** : Pharmaceutical Industry, meeting future Challenges	**Chairman** : Mr. Ajit Singh, Associated Capsules Ltd., Mumbai **Co-Chairman** : Mr.R. Arivudainambi, Chennai
12.15	**Plenary Lecture 8** **Speaker** : **Dr. G.J.Rao**, University of San Malaysia, Malaysia **Topic** : Drugs affecting surfactant system of Lungs.	**Chairman** : Prof.Manjeet Singh, Punjab University, Punjab. **Co-Chairman** : Mrs.Shyamala Bhaskar, Al-Ameen College of Pharmacy, Bangalore

Auditorium 2 (Research and development/education)

09.00	**Symposium 12: Globalization of Pharmacy education - Where India stands?** **Speaker 1** : **Prof.O.Limuaco**, Centro Escobar University, The Philippines **Topic** : Pharmacy education in Philippines coping with global trends with demand **Speaker 2** : **Dr.Neeraj Saxena**, Director, TIFAC Centre, Department of Science & Technology, New Delhi **Topic** : Role of TIFAC in bringing excellence in pharmacy education **Speaker 3** : **Mr. Simon Bell**, President, IPSF, The Netherlands **Topic** : Pharmacy education – a vision for the future **Speaker 4** : **Prof.B.G.Nagavi**, Principal, JSS College of Pharmacy, Mysore **Topic** : Harmonization of Pharmacy Education **Speaker 5** : **Dr.Samsinah H.Hussain**, Head, Department of Pharmacy, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia **Topic** : Pharmacy Education and the life long learner	**Chairman** : Prof. F. V. Manvi, Principal, KLE's College of Pharmacy, Belgaum **Co-Chairmen** : Prof.N.S.Parmar NIT, Ahmedabad Dr.Rajeev Dubae, JSS College of Pharmacy, Ooty
11.00	Tea Break	
11.15	**Symposium 15: Pharma Industry - Vision 2020** **Speaker 1** : **Dr.A.Sivathanu Pillai**, CCRD, DRDO, New Delhi **Topic** : India 2020 **Speaker 2** : **Mr.D.G.Shah**, Indian Pharmaceutical Alliance, Mumbai **Topic** : Pharma Vision 2020 **Speaker 3** : **Dr Ajit Dangi**, Director General OPPI, Mumbai **Topic** : Pharma vision 2020 **Speaker 4** : **Mr.Dara Patel**, Secretary General, IDMA, Mumbai **Topic** : Indian Pharmaceutical Industry Perspective **Speaker 5** : **Dr.G.J.Samathanam**, Department of Science & Technology, NewDelhi **Topic** : Funding Sources for Research in Drugs and Pharmaceuticals **Speaker 6** : **Dr.G.Padmanabhan**, Department of Science & Technology, NewDelhi **Topic** : International Cooperation Projects – A Step Nearer to Globalization	**Chairman** : Mr.Devinder Pal, Consultant Mumbai. **Co-Chairmen:** Dr.Himadri Sen, Vice President, Lupin, Pune Mr.B E Khomne, Joint Commissioner FDA, Thane, Maharashtra

Main Pandal (Panel Discussion)

09.00	**Panel discussion 3 :** **Small Industries : Post GATT implications in Pharmaceutical sector.** **Speaker 1** : **S.V.Veeramani**, Fourrts (India) Laboratories Pvt. Ltd., Chennai **Speaker 2** : **Mr.R.Tiruvengadam**, Tablets (I) Ltd., Chennai **Speaker 3** : **Mr.R.R.Shah**, Mercury Laboratories, Vadodara **Speaker 4** : **R.Sabapathy**, Medopharma, Chennai **Speaker 5** : **Mr.B.Prabhashankar**, VSP International, Hyderabad	**Coordinator :** Mr. S.S.Vanangamudi, Apex Laboratories, Chennai **Co-Coordinator :** Mr.L.V.Satyanarayana, Apex Laboratories, Chennai
11.00	Tea Break	
11.15	**Business meeting of CIPI**	

55th Indian Pharmaceutical Congress, Chennai
Scientific Oral and Poster Presentation

DECEMBER 19th 2003

Time 2.15 to 5.15 pm (Oral Presentations)					
No.	**Hall**	**Session(Mode)**	**Paper Nos**	**Chairperson**	**Co-chairperson**
O-1	Hall 2	Pharm Tech (Oral)	A1 - A18	Prof. KPR. Chaudhury, Waltair	Dr. A. Shirwaikar Manipal
O-2	Hall 3	Med Chem (Oral)	B1 to B18	Prof. M.R.Yadav Vadodara	Dr. P. Trivedi Indore
O-3	Hall 4	Biopharm & Pha.Kin (Oral)	F1 to F18	Prof. S.S. Agarwal, New Delhi	Prof. Gopal Krishnan, Coimbatore
O-4	Hall 5	Pharmacognosy (Oral) & Phytochemistry	C1 to C18	Prof. AK Saluja, V.V.Nagar	Mr. T.V.Narayana Bangalore
O-5	Hall 6	Pharm. Edn (Oral)	J1 to J18	Prof. Chandrasekaran Coimbatore	Dr. E.V.Subramaniam, Mangalore
Time 2.15 to 5.15 pm (Poster Presentations)					
P-1	Auditorium 4	Pharm. Tech (Poster)	AP1 - AP50	Dr. Venkateshwaralu, Waltair	Dr. R.H.Parikh V.V.Nagar
P-2	Auditorium 4	Hosp &Clin Ph. (Poster)	IP1 - IP51	Dr. S.K.Jain, New Delhi	Dr. Shobha Rani, Bangalore
P-3	Auditorium 4	Ind. Drugs (Poster)	DP1- DP51	Dr. (Mrs) Kasture, Nasik	Prof. NS. Jagannathan, Annamalai Nagar

Hall 1 : Preview Hall (for LCD and Slide verification)

55th IPC 2003
CHENNAI

55th Indian Pharmaceutical Congress, Chennai
Scientific Oral and Poster Presentation

DECEMBER 20th 2003

Time 10.00 to 1.00 pm (Oral Presentations)					
No.	**Hall**	**Session(Mode)**	**Paper Nos**	**Chairperson**	**Co-chairperson**
O-6	Hall 2	Pharm. Tech (Oral)	A19 to A36,	Prof AN Misra, Vadodara	Dr. Paradkar, BVPC, Pune
O-7	Hall 3	Pharmacology (Oral)	E1 to E18	Dr. M.N.Saraf, BMC, Mumbai	Mr. Arun Garg, New Delhi
O-8	Hall 4	Pharm.Anal (Oral)	G1 to G18	Dr. B.S.Shastry, Waltair	Dr. Raghurama Rao, Warangal
O-9	Hall 5	Ind. Drugs (Oral)	D1 to D18	Prof. M.Sukumar, Coimbatore	Prof. T. Subburaj, Ooty
O-10	Hall 6	Prof. Pharmacy (Oral)	K1 to K18	Dr. Bise, Aurangabad	Dr. Vasantha, Chennai
Time 10.00 to 1.00 pm (Poster Presentations)					
P-4	Auditorium 4	Pharm. Tech. (Poster)	AP51 to AP 100	Dr. Palani Swamy, Madurai	Dr. D.K.Jain, Indore
P-5	Auditorium 4	Med.Chem (Poster)	BP1 to BP50	Dr.AR Bhat, Belgaum	Dr. K.S.Jain, Pune
P-6	Auditorium 4	Pharmacognosy (Poster) & Phytochemistry	CP1 to CP50	Dr.M.D.Khariya, Sagar	Dr. Madhava Reddy Hyderabad
Time 2.15 to 5.15 pm (Oral Presentations)					
O-11	Hall 2	Pharm. Tech. (Oral)	A37 to A54	Dr P.R.Vavia, Mumbai	Dr. HG Shivakumar, Mysore
O-12	Hall 3	Med Chem (Oral)	B19 to B36	Dr Mrs R.Giridhar, Vadodara	Dr. S. Mohan, Bangalore
O-13	Hall 4	Regulatory Affairs (Oral)	L1 to L15	Mr Atul Nasa, New Delhi	Mr. Negi, NewDelhi
O-14	Hall 5	Pharmacognosy (Oral) & Phytochemistry	C19 to C37	Dr G. Ganapathi, Waltair	Prof. S. Ramanathan, Chennai
O-15	Hall 6	Hosp. Pharmacy (Oral)	I-1 to I-18	Dr. J.S.Dangi, Bilaspur	Mr. A.K. Adhikari, New Delhi
Time 2.15 to 5.15 pm (Poster Presentations)					
P-7	Auditorium 4	Pharm. Tech (Poster)	AP101 to AP120	Mrs Amrita Bajaj, Mumbai	Dr. Purushotam Rao, Gulbarga
	Auditorium 4	Biotech & Biotherap (Poster)	HP1 to HP20	Dr.SS Podar, Mumbai	Prof. S. Krishnan, Coimbatore
P-8	Auditorium 4	Pharm. Analysis (Poster)	GP1 to GP 50	Prof.SR Dhaneshwar, Pune	Dr. A.K. Sharma, Bariely
P-9	Auditorium 4	Pharmacology (Poster)	EP1 to EP 50	Dr R.K.Goel, Ahmedabad	Dr. Marihal, Goa

Hall 1 : Preview Hall (for LCD and Slide verification)

55th Indian Pharmaceutical Congress, Chennai
Scientific Oral and Poster Presentation

DECEMBER 21st 2003

Time 10.00 to 1.00 pm (Oral Presentations)					
No.	**Hall**	**Session(Mode)**	**Paper Nos**	**Chairperson**	**Co-chairperson**
O-16	Hall 2	Pharm. Tech (Oral)	A55 to A72	Dr. A.K. Madan, Rohtak	Prof. Srinath, Bangalore
O-17	Hall 3	Pharmacology (Oral)	E19 to E36	Dr. K. Elango, Ooty	Prof. Sudhakar Nair, Trivandram
O-18	Hall 4	Pharm. Analysis (Oral)	G19 to G36	Dr. S. Satyanarayana, Waltair	Dr. (Mrs) SJ Rajput Vadodara
O-19	Hall 5	Ind. Drugs (Oral)	D19 to D36	Mr. A.P. Purohit, Pune	Dr. KL Khandelwal, Pune
O-20	Hall 6	Biotech & Biotherap (Oral)	H1 to H18	Dr. Ellaiah, Waltair	Dr. Kishan, Warangal
Time 10.00 to 1.00 pm (Poster Presentations)					
P-10	Auditorium 4	Pharm. Edn (Poster)	JP1 to JP30	Dr. K.P. Busare, Nagpur	Prof. Shantha, Chennai
	Auditorium 4	Prof. Pharmacy (Poster)	KP1 to KP 20	Dr. D. Satyanarayan, Nitte Mangalore	Prof. Krantikumar Sirse Bidar
P-11	Auditorium 4	Pharmacognosy & Phytochemistry (Poster)	CP51 to CP100	Dr. Grampurohit, Mumbai	Dr. K. Kannan Annamalai Nagar

Hall 1 : Preview Hall (for LCD and Slide verification)

R.S.R. Murthy

Convener
Scientific Services Committee

Professor of Pharmaceutics
MS University of Baroda
Vadodara

Dr. R. S. R. Murthy is currently working as professor of Pharmaceutics in the department of Pharmacy, M.S.Universty of Baroda at Vadodara and as the co-ordinator of the TIFAC Center of Relevance and Excellence in New Drug Delivery Systems established by the department of Science and Technology , Govt. of India under mission Reach project under Technology vision 2020.

Born in 1949 in a small village in karnataka, was graduated in Pharmacy from Bangalore university . He obtained M.Pharm in Pharmaceutics from the university of sagar, Saugor, M.P. and PhD from Delhi university. After working for a brief period in Govt. college of Pharmacy at Bangalore, he joined College of Pharmacy, Delhi and served there up till 1986. He joined M.S.University as professor in 1988 and then served as Head of the department from 1990 to 1998. At present prof. Murthy is serving the university as senior professor and Co-ordinator of the " Center of relevance and excellence" in Drug Delivery Systems.

Prof. Murthy is an active researcher in the area of NDDS particularly in liposomes and nanoparticulate systems in drug targeting. So far he has guided 35 M.Pharm thesis and 7 PhD thesis and 7 scholars are working under his guidance for PhD. He has 45 major publication in national and International journals, authored chapters in three books and many popular articles. He has successfully turned out many projects in the field of NDDS for Governmental and Industrial organizations.

He has been associated with IPC activities as member of SSC since 1995. He has been appointed as the Convener of the SSC for three years from 2001. Often called as born teacher, Professor Murthy was honoured as " Teacher of the year " national award by the Association of Pharmacy Teachers of India for the year 2000. He was the associate editor of IJHP for a brief period in 1970s. He is on the panel of referees for the Journal of Pharmaceutical and biomedical Analysis, AAPS, IJPS & IJPE.

Prof. Murthy is on the panel of experts in various governmental agencies like CSIR, UGC, AICTE, UPSC, ICMR, DISR etc. and Board of studies & research degree committees of many universities in India.

Professionally, he is active since the beginning of his career. He was the president of IPA, Vadodara branch and is now the president of Gujarat state branch since 2000. He is also the life member of IPA, APTI, IPGA and member of CRS and IHPA.

Prof Murthy was honored in 2002 with the Indian Pharmaceutical Association Fellowship award during the 54th IPC at Pune.

Madhusudan Rao

Member
SSC

Professor
University College of Pharmaceutical Sciences
Kakatiya University
Warangal 506 009

Prof. Dr. Y. Madhusudan Rao has 25 years teaching experience. He has guided 6 scholars for Ph.D. 7 are working for a Ph.D. He has 46 publications and has presented 40 research papers. he has communicated 5 papers.

He has completed two research projects of AICTE worth Rs.16 Lakhs. Presently handling one major research project sanctioned by AICTE worth Rs.15 Lakhs and one major research project sanctioned by UGC worth Rs.7 Lakhs.

Earlier worked as head of the Department, Chairman of Board of studies, Dean, Faculty of Pharmaceutical Sciences, Warden of University Hostels, Member of Various Administration Committees like Senate, Library, Instrumentation etc. Worked as Principal and Head University College of Pharmaceutical Sciences, Kakatiya University, for 4 years. Presently is acting as a Member in-charge of Health Centers of University and National Chief Co-ordinator, Nodal Cell, Quality Improvement Programme for teachers in Pharmaceutical Sciences sponsored by AICTE.

Acted as co-ordinator for various Staff Development Programmes, Seminars workshops etc. Served as Chariman of various sessions in Pharmaceuticals and Biopharmaceutics of Indian Pharmaceutical congress. Serving as member 'scientific services committee' of Indian Pharmaceutical Congress Association from 1998.

S.H. Mishra

Member
SSC

Professor, Pharmacy Department
Faculty of Technology & Engineering
M.S. University of Baroda
Vadodara 390 002

Dr. S.H. Mishra is presently working as Professor, Pharmacy Department, Faculty of Technology & Engineering KalaBhavan. The M.S. University of Baroda and Vadodara 390002.

Prof. Mishra is a graduate in Pharmacy of 1969, Post graduate of 1972 and Doctorate in 1980 batches from Department of Pharmaceutical Sciences, University of Sagar, Sagar (M.P.)

Prod. Mishra joined as lecturer in Pharmacy in August 1772 and since 1988, is working as professor of Pharmacy. He has guided 29 Postgraduates and four Doctorates. He has handled various projects funded by MHRD, AICTE, and CSIR and is coordinator of Departmental Research Scheme of UGC under SAP. He has published 64 research papers in both National and International journals. He is Joint Secretary of Indian Society of Pharmacognosy. He is member on selection and academic committees of various Universities and also of AICTE.

Prof. Mishra is recently nominated as member of Pharmacy Council of India as UGC nominee.

B. Suresh

Member
SSC

Pincipal
JSS College of Pharmacy
Ootacamund

President, PCI, New Delhi

Dr. B. Suresh, M.Pharm., Ph.D., FIC, is presently working as Principal and Professor of Phrmacology at JSS College of Pharmacy, Ootacamund, Tamilnadu since 1993. Recently he has been elected as president pharmacy council of India, New Delhi. He has also worked as Cheif Executive Officer at Center of Relevance and Excellence in Herbal Drugs. He is a Honorary Member of AICTE, DTE, PCI, New Delhi and many other important university and Government bodies. He is also President, Tamilnadu State Pharmacy Council, Chairman of Pharmacy Education Divison, Federation of Asian Pharmaceutical Association (FAPA) and Indian Pharmaceutical Association, Education Division. He is a member of Editorial board of Indian Journal of Pharmaceutical Sciences, Pharma Times and Indian Journal of Pharmaceutical Education and a life member of many national and itnernational organizations and bodies. He is consultant to many Indian and American Pharmaceutical industries.

Dr. B. Suresh has about 190 research papers to his credit, published in National and International journal. He has authored four books in Pharmacy, guided 38 M.Pharm students and presently guiding 7 students for their Ph.D. He visited several countries and traveled extensively throughout the worked for delivering talks on various topics, and on educational exchange program. he has successfully organized many seminars and conferences in and outside Ootacamund. His current research interest includes validations and Revitilazation of traditional medicines and Herbal drugs.

Prakash V. Diwan

Member
SSC

Scientist 'F', Pharmacology Division
Indian Institute of Chemical Technology, Hyderabad 500 007

He is involved in developing technologies and commercialization of herbal formulation useful as a therapeutic and cosmetic applications for the treatment of general skin disorders, novel drug delivery, oral insulin therapeutic peptides and vaccines, compositions and complexe containing a macro molcular compound as potential anti-inflammatory agents, therapentic edible compositions comprising herbal ingredients. He is also the Technical consultant for several laboratories a member of several professional bodies.

M.N.A. Rao

Member
SSC

General Manager - R&D
Divis Laboratories Limited
Hyderabad

Dr. M.N.A. Rao is the General Manager, R&D, at Divis Laboratories Limited, Hyderabad since six years. He is involved in the process development of amino acid derivatives, nucleotides, chiral molecules, etc. Before joining Divis, he was professor of Medicinal chemistry at College of Pharmaceutical Sciences, Manipal for 15 years. He was also vice-principal and acting principal. Earlier, he also taught at BITS. Pilani for 6 years.

He obtained his B.Pharm. from GCP, Bangalore and M.Pharm. & Ph.D. (Under Dr. B.M. Mithal) from BITS, Pilani. He was CSIR scholar at CDRI, Lucknow.

He has guided 7 Ph.D. and has 82 research publications. He has won "Good Teacher Award" at Manipal and Best Paper award in Pharmaceutical Chemistry in Indian Drugs from IDMA. He was the Editor of Ind. J.Pharm. Education (I.J.P.E.). He has acted as a referee for Bio-Organic & Medicinal Chemistry, International J. Pharmaceutics, Life Sciences, Drug Investigations, IJPS, IJPE, etc. He is a life member of APTI & IPA.

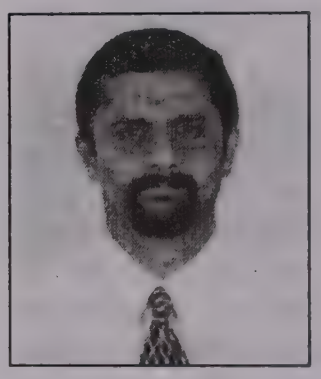
K. Kannan

Member
SSC

Dean, School of Biotechnology
Gurugovind Singh
Indraprastha University
New Delhi 110 006

Prof. K. Kannan has had varied experience of over two decades as a Scientist, Professor, a senior corporate executive and as an advisor / consultant in the filed of Biochemistry, Biotechnology, Dairy Technology, Medical Technology, Immunology, Stem Cell Biology and Haematopoeisis. He is the national convenor for Biotechnology for school children under CBSE. He has been the major contri butor for class XIth. He has held the position of Associate Director (Biotechnology) in the largest pharmaceutical company in India as well as Director of the largest Indian diagnostic company. During his tenure of 11 years in the industry, he has focussed in the are of medical technology with a view to developing several medical devices as well as quality assurance parameters of use to the medical practitioners. He has advised several companies to market their products for manufacturing R&D and marketing. Commercialized the indigenous production of whey per day using ultrafilteration. He was a National science Talent Scholar and was invited to join the faculy at the Center for Celluar and Molecular Biology, a center of excellence as a senior scientist in 1982. Besides academic activities, he is also the Dean of student's welfare and holds the biggest cultural festival in Delhi during the first week of February every year.

G. Parthasarathi



Member
SSC

Professor & Head
Department of Pharmacy Practice
JSS College of Pharmacy
Mysore

Dr. Parthasarathi completed M.Pharm., in Pharmacology from Govt. College of Pharmacy, Bangalore in 1989; finished Ph.D. in 1994 and Masters degree in Clinical Pharmacy in 1997 from University of South Australia, Adelaide. He received his training in Clinical Pharmacy at Repatriation General Hospital, Adelaide and was awarded "Weary Dunlop" Fellow in Clinical Pharmacy from same hospital.

After returning to India in 1997 April, he started this new discipline, Clinical Pharmacy practice and education at JSS Hospital, Mysore. He has been very successful in this endeavor. His department basically addresses any drug-related problems. For his innovative thoughts and ideas in Pharmacy Practice in Indian set up he was awarded with "Young Teacher of year 2000" award from APTI.

Dr. Parthasarathi has fifteen research papers to his credit in national and international journals; has presented papers in national and international seminars /conferences; has participated as resource person in many workshops & has delivered several guest lectures. 3 of the research papers where he a co-author has won the best paper awards. His research interests are in the areas of Adverse Drug Reactions, Quality of life studies in different diseases and drug usage evaluation especially antibiotics.

Local Scientific Committee

- Brief Resume

T.K. Ravi

Chairman
Scientific Services Committee (LOC)

Principal, College of Pharmacy
SRIPMS, Coimbatore 641 044

He has completed B. Pharm & M.Pharm from the COPS, Manipal & Doctorate from Mangalore University. He has 17 years of teaching and research experience. He is Chairman of Pharmacy Faculty, member of the Governing Council, Senate and Standing Academic Board of The Tamil Nadu, Dr. M.G.R. Medical University, Chennai. He was awarded with the distinguished Alumni Award from the COPS, Manipal for the year 2001. He was the organising secretary of the 4th APTI convention conducted at Coimbatore. He is in the Board of Studies of MAHE and MG Universities. He has 30 publications in National & International journals & presented severals papers. He has guided 25 M.Pharm. students and presently guiding 6 scholars for Ph.D programme. He is life member of APTI, IPA, IPGA, etc. He was the IPCA Scientific Committee Member from 1998 to 2000.

M. Ramanathan

Co-Chairman
SSC (LOC)

Assistant Professor
Department of Pharmacology
JSS College of Pharmacy
Ootacamund

He did his M.Pharm. & Ph.D in Pharmacology from B.H.U. in 1998. He specialised in neuropharmacology. He received many awards to his credit, name few P.P. Suryakumari Prize for the best research carried out in diabetics in 2000, Young Scientist fellowship award in 2000, invited as Guest Scientist, BMBF, Germany to work in Dept. of Physiological Chemistry, received International Branch Research Organisation fellowship for Asian Oceanic regions to carryout research work in neuroscience. Received travel grant award from Asian Neuroscience Society. He has published 22 papers in referred journals and presently guiding 3 PG & Ph.D. Students.

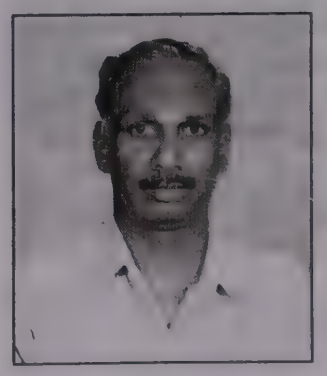
C. Uma Maheswara Reddy

Co-Chairman
SSC (LOC)

Professor
Sri Ramachandra College of Pharmacy
SRMC&RI (Deemed University)
Chennai

He completed B.Pharm and M.Pharm from Andhra University and Ph.D from Sri. Ramachandra Medical College and Research Institute, Chennai. He has got 17 years teachning experience and has undergone practical training in Quality control and manufacturing Dept., Rallies India Ltd, Bombay. He has attended several workshops and conferences held at national level. He is a life member of many Associations like APTI, IPA, IHPA, ISTE and IPS. He has co-ordinated A.I.C.T.E sponsored ISTE programme on Drug Development. He is the Co-chairman for the Scientfic Services of IPC 2003.

Balasubramanian



Co-Chairman
SSC (LOC)

Reader
Faculty of Environmental Sciences
Bharathiar University
Coimbatore

He completed his M.Sc., M.Phil. and Ph.D. from the University of Madras. He is academically affiliated to Remote Sensing and Geographic Information Systems, Ecotoxicology and Water Resource Management and Ecological Modelling. His areas of expertise include Mathematical Models, Water & Pest Management, Eco-Toxicology and Geographic Information Systems and Remote Session. He has 46 publications to his credit and has guided 10 Ph.D & 15 M.Phil students and currently guiding 6 research scholars.

A. Rajasekar

Member, *SSC (LOC)*

Principal
Arulmigu Kalasalingam
College of Pharmacy
Krishnan Kovil, Srivilliputtur

He has completed B.Pharm. in 1987, M.Pharm. and Ph.D. from BITS, Pilani in 1989-2001 respectively. He has 37 research papers in international & national journals. He has presented 19 papers in conferences. He has guided 7 M.Pharm. students for their dissertation work. He has 15 years teaching experience.

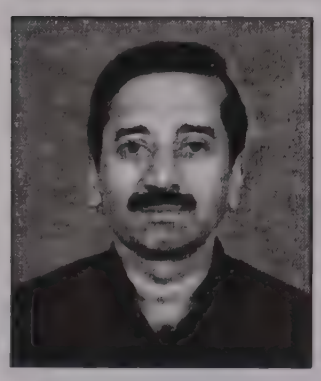
V. Murugan

Member, *SSC (LOC)*

Asst. Professor
Department of Pharmaceutical Chemistry
JSSCollege of pharmacy
Ooty

He has completed M.Pharm. from JSS College of Pharmacy, Ooty in 1990 & has 13 years teaching experience. He had Visited the University of Regensburg, Germany for three months under the Indo-German Collaborative project. He has guided 13 M.Pharm. Scholars and had 12 Publications to his credit in both National and International Journals.

S. Krishnan



Member, *SSC (LOC)*

Professor & Head
Department of Pharmaceutical Biotechnology
College of Pharmacy
SRIPMS, Coimbatore

Completed his M.Pharm. in 1989 from COPS, Manipal with University I Rank, B.Pharm. in 1986 & D.Pharm. in 1982 from COPS, Manipal with IV Rank in state. He has 16 Presentations at National Conferences, of which, two were adjudged Best & Second Best presentation respectively. He has 3 publications and has guided 14 students for their M.Pharm dissertations.

S. Kuppusamy

Member, *SSC (LOC)*

Associate Professor
Department of Pharmaceutics
College of Pharmacy, SRIPMS
Coimbatore 641 044

Completed M.Pharm., from College of Pharmacy, SRIPMS in 1995 after completing B.Pharm. in 1987 and D.Pharm. in 1981 at present doing his Doctoral Programme. He has guided 12 M.Pharm. students. He has attended & presented papers in National Conferences.

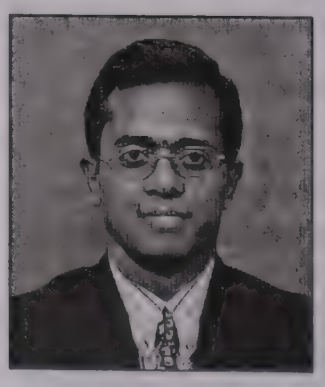
S. Kavimani

Member, *SSC (LOC)*

Reader
Department of Pharmacology
College of Pharmacy
Mother Therasa Institute of Health Sciences, Pondicherry

He is an M.Pharm., Ph.D., from Jadavpur University, Calcutta & published 69 Research papers in National & International Journals. He presented 25 papers in scientific conferences. He has guided 10 PG students. He worked in various Research projects sponsored by AICTE and DRDO.

S.S. Shriram



Member, *SSC (LOC)*

Assistant Professor
Department of Pharmacy Practice
College of Pharmacy, SRIPMS
Coimbatore 641 044

Completed B.Pharm. in 1990 and M.Pharm. in 1995 from JSS College of Pharmacy, Ooty securing Gold Medal. He has 3 years of Marketing Experience. He guided 6 batches B.Pharm. Students and 7 M.Pharm. students. He has published one International & 12 Papers in National Journals and currently doing doctoral programme.

C. Uma Maheswari

Member, *SSC (LOC)*

Lecturer, Sri Ramachandra College of Pharmacy
Sri Ramachandra Medical College & Research Institute
Deemed University, Porur, Chennai

She has completed M. Pharm from BITS Pilani in 1990 & M. Pharm from The Tamil Nadu Dr. M.G.R. Medical University 1999. She has teaching experience of 15 years.

Sumita Singh

Member, *SSC (LOC)*

Assitant Professor
Dept. of Biotechnology
College of Pharmacy
SRIPMS, Coimbatore.

She is a Ph.D. (Immunology) from Sanjay-Gandhi Post Graduate Institute of Medical Sciences, Lucknow in 1997. She has 11 international publications.

B. Rajalingam

Member, *SSC (LOC)*

Assitant Professor
Dept. of Pharmacy Practice
College of Pharmacy, SRIPMS
Coimbatore

He completed M.Pharm from JSS College of Pharmacy, Ooty. He has 7 years of teaching experience.

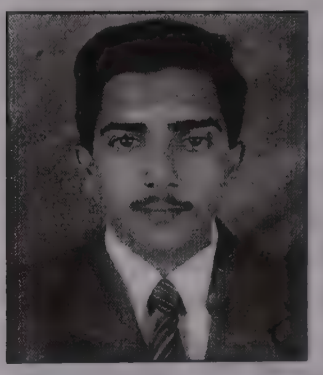
Sapna Shrikumar

Member, *SSC (LOC)*

Assistant Professor
Dept. of Pharmaceutical Analysis
College of Pharmacy, SRIPMS
Coimbatore

She completed M.Pharm. from JSS College of Pharmacy, Ooty, and undergoing her doctoral programme. She has 8 years of teaching experience and guided 8 PG Students.

P. Ramasubramaniyan



Member, *SSC (LOC)*

Lecturer
Sri Ramachandra College
of Pharmacy, SRMC&RI, Chennai

He completed his M. Pharm from Annamalai University. He has teaching experience of 4 years.

Manjula Devi A.S.

Member, *SSC (LOC)*

Assitant Professor
Dept. of Pharmacy Practice
College of Pharmacy
SRIPMS, Coimbatore,

She completed her M.Pharm from College of Pharmacy, SRIPMS, Coimbatore. She has 7 years of teaching experience.

S. Shanmuganathan

Member, *SSC (LOC)*

Lecturer
Sri Ramachandra College
of Pharmacy, SRMC&RI, Chennai

He completed M. Pharm from Annamalai University. He has four years of teaching experience.

M.D. Nair

Consultant to
Pharmaceutical Industry
A-11, Sagarika
15, 3rd Seaward Road
Valmiki Nagar
Chennai 600 041, India

Dr. M.D. Nair, has a Ph.D Degree from the University of Illinois, USA. He was a Fulbright Scholar, a Fellow of the National Research Council of Ottawa, Canada, Alfrd P.Sloan Research Foundation, New York and Research Associate at University of Illinois, before joining the Pharmaceutical Research Group of CIBA Limited, Switzerland, and later of Ciba-Geigy Research Centre in Bombay.

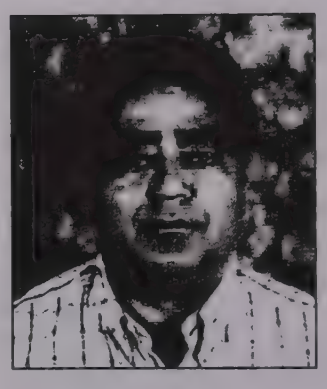
Dr. Nair, who was later, the Vice President of SPIC, was instrumental in setting up of SPIC as one of the largest antibiotic complexes in India, a 'state-of-the-art' Pharmaceutical R & D Centre.

Besides authoring over 80 publication in various national and international journals, he is the holds several patents on new therapeutic agents and has co-authored three books published by Academic Press, John Wiley, Birkhauser, etc. He is the author of Indian Pharmaceutical Market Guide 1998 published by PJB Publications, London and has contributed to the Unviersity Text Book entitled "International Business Law" publshed by ITP, Washington, Pharmacists Year Book, New Delhi, Saket's Pharma Hand Book, Ahmedabad etc.

He has been a Consultant to WHO for setting up Pharmaceutical Projects in Arab countries and on Traditional Medicines in New Delhi, Bangkok and Jakarta; Member of Delegation to USSR for developing Indo-USSR Collaborative Projects in Pharmaceuticals; Member of the High Power Delegation on Indian Economic Mission to Belgium; Consultant to Commonwealth Secretariat for Developing Pharmaceutical Industries in Eastern and Southern African State, etc.

He has been an Advisor to Government and Private Organisations on Science and Technology and Director of the Boards of many Pharmaceutical Companies, Governing Councils of various Academic Bodies, Universities and Medical Institutes, Panels of Council of Scientific Research, Indian Council of Medical Research, All-India Council of Technical Education, Export Promotion Council of India, etc. He is an Honourary Professor at the Department of Biotechnology, Anna University, Chennai and a Member of the Task Forces for Pharmaceutical Industry and Biotechnology in Andhra Pradesh, Gujarat and Kerala States. He is a Member of several National Committees of the Central Government including the Mashelkar Committee of reorganising the Drug Regulatory Agencies in the country.

Adeep Bagati



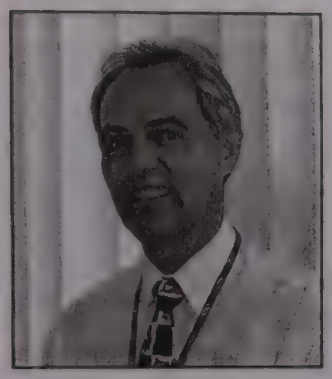
Vice-President
R&D, Cadila Pharmaceuticals Ltd
Ahmedabad

Dr. Adeep has more than 17 years experience in Manufacturing / Institutional Hospital Pharmacy / Management and Clinical Research. Strong back ground in Good Clinical Practice (GCP) Research & Bioequivalence studies. Hands on experience in Licensing, IND, NDA submission, Regulatory Affiars and liaison with Government officials.

Dr. Adeep Bagati has completed his Ph.D. in Pharmaceutical Medicine. He completed his B.Pharm and M.Pharm from University of Delhi with 1st Division and Gold Medal in M.Pharm. Currently he is the Vice-President, R&D of Cadila Pharmaceuticals Ltd. He is responsible for the overall Regulatory Affairs in India both at OCGI level and state FDA's level, developing and maintaining effective liaison with Drug Control Administrations, Allied Health authorities to obtain Manufacturing and Marketing approvals on time.

Dr. Adeep has attended various pharmaceutical conferences, Orientation Courses in various parts of Saudi Arabia, United Kingdom and India. He was awarded as 'Unique Person' by the Director of Health Affairs, Hafr-Al-Batin, 1987, K.S.A. He was nominated as an Expert to the Bureau of Indian Standards (BIS) Quality Systems Certification Scheme (QSCS) Committee.

Malcom Patridge



Chief Pharmacist
Queen's Medical Centre
Nottingham
NHS Trust, NG 7 2UH

Malcolm Partridge registered as a pharmacist in 1975 after graduating in Leicester. He went on to establish Leicester's first resident pharmacy scheme and was their first staff pharmacist for clinical pharmacy service development. During this time he was successful in obtaining an MSc in Pharmacotherapeutics. In 1982 he took time out to undertake a research project over 3 years in which he developed a novel in vitro cytotoxicity test for new anticancer agents and this led to his PhD award in 1987. He moved to Liverpool in 1985 to become their first teacher –practitioner during which time he developed an interest not only in Education and Training but also in paediatrics at Alder Hey Children's Hospital which was his clinical practice base.

In 1994 along with others he became a founder member of the Neonatal and Paediatric Pharmacists Group and was recently their Chairman for 4 years. NPPG now has an international membership.

Following a move to Derby in 1996 he helped establish a new MSc in Clinical Pharmacy with the University of Derby before becoming Chief Pharmacist at Derby City and Derbyshire Children's hospital. He was appointed Chief Pharmacist at the Queen's Medical Centre University Hospital, Nottingham in May 1999 where he has taken a leading role in the development of systems for medicines management.

P.D. Sheth

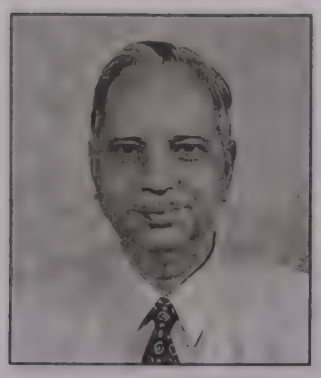
President
Indian Pharmaceutical Association
Mumbai

P.D. Sheth born on 8th February 1939 in Mumbai, completed his B.Sc (Chemistry) from the University of Bombay and B.S. (Pharmacy) and M.S. (Pharmacy) fom the University of Missouri at Kansas City. He has served in various capacities in leading pharmaceutical concerns including Executive Vice-President and member board of Ranbaxy Laboratories Ltd., New Delhi. He is The President, IPA, Mumbai and Vice President, Federation of Asian Pharmaceutical Associations, Manila, Philipines.

Mr. Sheth has also undertaken various pharma projects for World Bank, UNDCP, UNIDO and National Human Rights Commission. He is associated with Ranbaxy Community Health Care Society, Drugs Technical Advisory Board, Working Group on AIDS and Drug Addiction of FIP. As Observer developing countries, Mr. Sheth has undertaken a project on developing and implementing guiding principles for pharmacists in fighting HIV/AIDS in India. He is a Member Board of Trustees, Delhi Pharmaceutical Trust and Convenor of Pharmaceutical Discussion Group, Delhi. He is an Honorary Advisor of the Delhi Society for the Promotion of Rational Use of Drugs. He is a Member of an Expert Committee, setup under the Chairmanship of Dr.R.A. Mashelkar ofr New Structure of Drug Regulatory System in the Country and to Measures required to deal with Spurious drugs.

Mr. Sheth is a fellow and eminent pharmacist of the Indian Pharmaceutical Association. He was honored with The Acharya P.C. Ray Memorial Gold Medal for outstanding contribution to the profession of pharmacy by Bengal Branch of the Indian Pharmaceutical Association.

C.K. Kokate



Vice - Chancellor
Kakatiya University
Warangal 506 009

Prof (Dr.) Kokate was born on 15th August 1947 and is currently the Vice-Chancellor, Kakatiya University, Warangal. Dr. Kokate completed his M.Pharm from University of Sagar in 1969 and Ph.D. in 1972 in Pharmaceutical Sciences in 1972. He is the only pharmacists in India to have held four National positions simultaneously, namely

1) *President, Pharmacy Council of India*
2) *National President, Indian Pharmaceutical Association*
3) *Chairman, All India Board of Pharmacy of AICTE*
4) *Executive Committee Member, AICTE.*

Dr. Kokate has authored five books of which one book 'Pharmacognosy' is in twenty-fifth edition and is used as a text book in several Indian and foreign universities at U.G. and P.G. levels. He has successfully guided 15 students for Ph.D. and 40 students for M.Pharm. Dr. Kokate has to his credit 110 research papers in leading international and Indian Scientific Journals and 65 papers at National conferences. His biographic sketch is included in Who's Who of the three International Publications. He is receipient of several awards including Prof. G.P. Shrivastava Memorial National Award 1994, Shri. B.V. Patel Memorial National Award 1997, Prof. M.L. Schroff National Award 1999 and Indira Priyadarshini Award 2001. He is an expect for UPSC, UGC and Public Service Commission for three states. He has served as a member of QRT Committee of Indian council of Agricultural Research, Government of India.

Subodh Priolkar

Director
Valois India Limited
407, Madhava
Sandra Kurla Complex
Bandra (E), Mumbai 400 051

Subodh Priolkar graduated from Bombay College of Pharmacy in 1978. He also has a post graduate degree in Business Management from University of Mumbai. He was selected for the UNIDO sponsored programme on Pharmaceutical Technology in University of Ghent, Belgium. He also has done a post graduate diploma in Operations Management from J. Bajaj Institute of Management.

Worked in Abbot Laboratories for few months and joined Wyeth Lederle Ltd. after having a long stint with the company, at the time of leaving, he was Associate Director, Manufacturing, responsible for total manufacturing of the company. Currently, he is Managing Director of Valois India Pvt. Ltd. - a French Multinational Company.

Mr. Priolkar has been associated with IPA for more than 12 years. Having served IPA in many capacities, he is past President, IPA, Maharashtra State. Currently he is Chairman, Industrial Pharmacy Division, IPA. He has also been on many committees of IPA-Centre. He is the Chairman of the governing body of the Bombay College of Pharmacy. He has represented OPPI on presentations made to Drugs Controller General of India on the issues related to Drugs and Cosmetics Act. He was on the core committee for the first national convention of Industrial Pharmacy in Mumbai. He was the Hon. Joint Secretary for the 50th IPC which was held at Mumbai in Dec. 1998.

Mr. Priolkar is known for his energetic and active perusal of the projects with which he gets involved and for his administrative capabilities. He has widely travelled through out the world.

Vivek Kapur

Group Leader, International Drug Regulatory Affairs
Ranbaxy Laboratories Limited
A-10, Phase 3 Industrial Area
SAS Nagar (Mohali)
Punjab 160 055. India

Having over a decade of hands-on experience in International Regulatory filings all over the world. Over 500 generic dosage forms and active pharmaceutical ingredient filings, approvals and post approval change management to his credit. Has been on an International assignment in Europe and have dealt directly with EU regulators on issues of Marketing authorization applications (MAAs), Mutual recognition procedures (MRPs), Parallel/ Piggyback licensing and Variation filings & approvals.

He handled regulatory affairs & change control management for European dosage form manufacturing facility (Ranbaxy, Ireland) and currently managing DMF filings for active pharmaceutical ingredients (APIs) including post approval changes & Regulatory compliance for APIs manufacturing facilities.

Dnyanesh Arun Limaye

Head, Drug Regulatory Affairs
Aventis Pharma Ltd
54/A, Sir Mathuradas Vasangi Rd.
Mumbai 93.

Dr. Dnyanesh is the Head of Drug-Regulatory Affiars and General Manager of Aventis India. He is involved in preparing on line dossiers for new product registration and online data submission for local as well as global clinical trails. His interest include imparting business advantage by accelerating new product registration and approvals for clinical trials which is immensely helpful in the investigation of new drugs. He is currently monitoring 8 global trials and 3 domestic PMS studies. In addition, he is involved in the development of software for Global Drug Registration activities and has completed training in Aventis International, Paris.

He has contributed in enhancement of Export Business of New products by developing the Export Registration Software for Non-regulated markets. He served as a medical advisor in scientific communications, Newzealand, and Wockhard Limited from 1999 - 2002. As a manager in medical services, Fulford India Ltd., he was actively engaged in Clinical Research, ADB reporting, preparation of medical literature product manuals and therapeutic index for various products. He is a recipient of various prestigious fellowship from USA, University of Bombay, UGC-India and National merit scholarships, India. He has attended several International conferences and presented papers in Vietnam, France etc. He has to his creidt over 25 publications.

Dr. Raghavendra Rao

Managing Director
Orchid Chemicals &
Pharmaceuticals Ltd., Chennai

Mr. Rao obtained a Post-Graduate Diploma in Management from IIM-Ahmedabad in 1979 which was aided by a National Merit Scholarship.

He started his career as the Financial Controller of Pure Ice Creams in Bombay (now Mumbai), where, his innovative inputs in the areas of accounting, auditing and MIS resulted in a 300% increase in the turnover of the group between 1979 and 1981.

In November 1981, Mr. Rao moved to Ashok Leyland, Madras where, as Assistant Manager - Corporate Finance, in addition to introducing and implementing innovative concepts, he also found time to complete the ICWAI and ACS courses.

Moving on, he then joined Standard Medical and Pharmaceuticals Limited, Hyderabad, belonging to the Standard Organics (SOL) Group as Vice President. Mr. Rao's next move was to Muscat in November 1988 where he was the Director and Vice President of the Al Buraimi Group based in the Sultanate of Oman.

A salient achievement during his stint was the conception and commissioning of a 300-ton antibiotic manufacturing plant in a record time of 9 months. He returned to India in 1992 to promote Orchid Chemicals & Pharmaceuticals Limited.

In just ten years, Mr. Rao has transformed Orchid from a USD 14 million single-product company with a simple manufacturing facility to a USD 114 million multi-product operation and launched Orchid Healthcare, the Formulations division of Orchid to manufacture world class medicines for the Indian and world markets.

Established as a 100% Export Oriented Unit (EOU), Orchid has notched up a turnover of over USD 114 million and achieved a global leadership in the pharmaceutical bulk actives segment. His dynamism and entrepreneurial drive were recognised and rewarded when he was awarded the India Young Business Achiever Award in 1997.

Mr Rao was recently awarded the prestigious Entrepreneur of the year Award for Manufacturing in 1999 by Ernst & Young International.

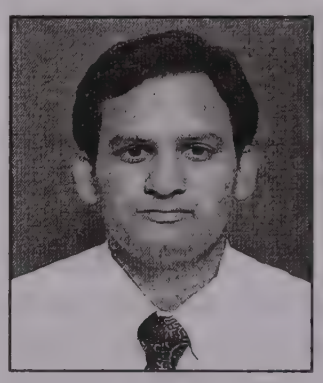
Mr. Raghavendra Rao was chosen as "The Outstanding Alumni", by his Alma Mater VSR & NVR College, Tenali in November 2000. The Pharma Business and Technology magazine recently honoured Mr Raghavendra Rao as the most Dynamic Entrepreneur of the year 2002.

Bailoore Gopalakrishna Kini

B-401, Shantiswarup
NP Thakkar Marg
Vileparle-East, Mumbai 400 057

Bailoore Gopalakrishna Kini is a graudate in Chemistry and MSc in Analytical Chemistry. He also possesses Management degrees namely DBM and MAM. He is an approved chemist by the FDA, Mumbai in Chemical & instrumental analysis, Pyrogen and toxicity testing. He underwent completed one week training program on Auto analyzer sponsored by M/s. Technicon (Freland) UK in the year 1988. He also visited Waters Chromatography Division USA. Dr. B.G. Kini has vast experience and training on preparing facilities for US FDA approval, fundamentals and essentials of validation, GMPs Effective QA auditing master validation plan, Qualification summary etc. He attended several GMP training program in National and International level. He visited several countries for different business and technical purposes. He has experience in the pharma division of various multinational companies in India and Abroad.

Sachin Itkar



Managing Director
Bill Care Pharma Packaging
Research, Plot 365, Sector 24
BH Sant Tukaram Sankul
Nigdi Pradhikaran, Pune 44

Graduated in Pharmacy from Govt. College of Pharmacy, Karad in first division (69.00%). Successfully completed MBA (International Business) first class with distinction (78.00%) from Institute of International Business & Research, Pune. The project entitled "To study the prepardness of Indian Pharma Industry to face the Post 2005 Era was awarded the first prize for the year 2001-2002 by IIBR.

Published articles in Pharmabiz, Pharmapulse & IPC Souvenir 2002 on 'Biotechnology & Intellectual Property Rights" and "issues related to IPR - Implications to Indian Pharma Industry' was invited by Bharti Vidyapeeth's Poona College of Pharmacy to deliver a lecture on 'Intellectual Property Rights-Implications to the Indian Pharma Industry' in AICTE faculty development programme may 2002.

Delivered lecture on 'Biotechnology & IPR in National Biotechnology Conference organized by Singhgad College of Pharmacy, Pune in September 2002. Participated in many National & International conferences. A life member of Indian Pharmaceutical Association & an active member of IPA, Pune branch.

The biggest achievement of the career so far, is the opportunity to work as an 'Event Manager' for the 54th Indian Pharmacy Congress, Pune 2002 was felicitated by the Organizing Committee of 54th IPC for the successful efforts to make the event a grand success.

Presently working with Bilcare Pharma Packaging research, Pune as 'Executive Assistant to President-marketing and Research.

Venkat Jasti

Managing Director
Suven Pharmaceuticals Limited
205, Srinilaya Estate
Ameerpet, Hyderabad 73

Mr. Venkat Jasti holds a Master degree in Pharmacy from Andhra University and M.S. in Industrial Pharmacy, St. John's University, NY, USA. Mr. Jasti started his career as a Production Officer in Warner Hindustan Limited and later on migrated to USA wherein he owned and operated a chain of 6 community pharmacies in the United States for 12 years. He came back to India and established Suven Pharmaceuticals Limited in the year 1989 and is the Founding Managing Director, a company which specializes in ***'Contract Research and Manufacturing Services*** *(C-R-A-M-S), now renamed as Suven Life Sciences Limited.*

Mr. Jasti has been the ***Past President*** *of Indian Pharmaceutical Association, Andhra Pradesh State Branch,* ***Chairman*** *of Local Organizing Committee for the 52nd Indian Pharmaceutical Congress, held at Hyderabad and presently is the* ***President*** *of* ***Bulk Drug Manufacturers Association, India (BDMA).*** *Mr. Jasti is also the* ***Cheif Architect*** *for the formation of A.P. Chief Minister's task force for Pharma and member of the same wherein Centres of excellence in Manufacturing, R&D and clinical research will be set up.*

He has served the community as a community pharmacist in the US for over 12 years and actively participated in IPA activities right from 1989 after returning from USA as a member of executive committee of IPA, A.P. State Branch. He was instrumental in bringing Pharmaceutical Technology to the forefront of A.P. States main technology thrust on IT, BT and PT.

As a member of the Pharma Task Force of AP, Mr. Jasti is actively involved in the formation of a Pharma City, near Visakhapatnam, in lines of the concept of exclusive parks that exist in Singapore and China with public private ownership.

D.B.A. Narayana

Head Herbals Research
Hindustan Lever Research Centre,
Andheri, Mumbai & Managing Trustee
Delhi Pharmaceutical Trust.

Dr. D.B. Anantha Narayana is a gold medallist at both his Pharmacy Degree Exam from Bangalore College of Pharmacy as well as his Masters Degree in Pharmacy from University of Sagar (M.P.). As head of Herbals Research at HLRC, Dr Anantha Narayana is responsible for scientific development related to the Ayush portfolio. He is also involved in development of naturals for use in HLL's Ayurvedic as well as non-Ayurvedic products.

He is a member of ASU-DTAB of Ministry of Health, and a working group member of Indian Pharmacopoeia and many other committees of Govt. of India.

Dr. Anantha Narayana taught at Saugar (M.P.), Hamdard College of Pharmacy (New Delhi), and then at College of Pharmacy New Delhi where he obtained a Ph.D. from Delhi University in 1980.

In 1991, Dr. Anantha Narayana joined Dabur where helped set up and guide research and development work at Dabur Research Foundation (DRF) at Sahibabad (U.P.). He has led development of a number of products based on Ayurvedic Knowledge, which found successful marketing through both FMCG as well as Ethical routes of marketing.

Dr. Anantha Narayana has many patents and books to his credit. He has delivered lectures at various reputed educational institutions as well as professional forums.

Atul Shirgaonker

Insight System, Flat No. 5
1st Floor, Vinit Building
Plot No.20, Alkapuri, Paud Road
Kothuid, Pune 38

Mr. Atul Shrignonkar has completed his M. Pharm from Haffkine Institute, Mumbai. He has served the pharma industry in various disciplines and capacities for nineteen years. He has conducted more than five hundred and seventy five training programmes in functional, technical and behavioural aspects of management. He is assocaited with management and quality of various leading multi nationals like Novartis, Zydus Cadila, Torrent, Aventis, Ranbaxy and Apollo Tyres.

Gauri Chaudhari

Head
Strategic Planning Consultant
FCB - Ulka Health Care

She completed her B.Pharm with distinction and did Masters in Management from the Bombay University. She has successfully completed courses in Imports and Exports Management, Advertising and Multimedia.

She has a teaching experience from 1999. She is instrumental in establishing FCB-Grid which is a proprietary tool to develop effective communications in the consumer industry. The Grid was successfully extended to pharmaceutical brands to give clear ductions towards developing brand communictions. At FCB, she developed a method to arrive the right brand name that connotes the right message, makes the right impact and most importantly easy to remember. She is also the member of Advertising Club of India and Market Research Society of India.

Brijesh Regal

Fellow of IPA
Chairman of Community Pharmacy Division IPA
Managing Pharmacist
Apothecaries Limited

Mr. Brijesh Regal, an M.Pharm. from Delhi University, is currently a W.H.O. Consultant to the Drugs Controller General of India. He has been the Chairman of Community Pharmacy Division of Indian Pharmaceutical Association and the National Vice President of IPA. Formerly he has been the Pharmacy Services Consultant to the US Embassy in New Delhi.

The computer-assisted-pharmacist-based operation system evolved by him focuses the retail pharmacy functions on patients rather than products. The 'PharmAssist' programme conceptualized by him for Indian socio-economic scenario is setting new standards for 'Managed Pharmaceutical Care' for the patients at the Model Pharmacy a set up in collaboration with Hamdard University, New Delhi. He actively participates in imparting training to the pre-registration pharmacists as well as registered pharmacists at the Model Pharmacy.

Over the last 6 years he has played an influential role in the emergence of Community Pharmacy concept in India. Through hundreds of workshops conducted across the country over the last 5 years - he has been invoking the retail pharmacists to professionalize their operations to make them relevant to the health-care of society.

Paul Heng Wan Sia

Head, Department of Pharmacy
Associate Professor in Pharmaceutics
Teaching staff with National University of Singapore since 1984
www.gean.nus.edu.sg.

Dr. Paul Heng is presently the Chairman and Quality Control Advisory Committee, Min of Health, Singapore and visiting Professor of Shenyang Pharmaceutical University, China. He is also an efficient Technical Assesor (Pharmaceutical Testing) for SAC-SINGLAS. The International Micro-Emapsulation Society has elected him as President. He is a member of the Singapore Pharmacy Board and holds an important post of Treasurer and Board Member, Asian Association of Schools of Pharmacy of he has over 80 international refereed journal articles on pharmaceutical processing and product development, in microencapsulation, spray drying, fluid bed granulation, fluid bed coating, controlled drug delivery systems, extrusion-spheronisation, rotary spheronisation and others. More than 80 conference and other non-refereed papers in similar fields.

M. Vasudevan

Director
CADRAT
JSS College of Pharmacy
Ootacamund, Tamil Nadu

Completed M.Pharm. in 1991 and Doctorate in Pharmaceutical Analysis 2001 from JSS College of Pharmacy, Ooty. He is the Director and Project Leader for Centre for Advanced Drug Research & Testing, Ootacamund. He is also Professor and Head, Dept of Pharmaceutical Analysis. He is Investigator or Co-investigator for industry and Government sponsored research projects. He has Published 25 papers in referred Journals and presented 45 papers in conferences, Organised 3 seminar cum workshop on HPLC for analytical chemists, Organised 2 international seminars on stability testing and regulatory requirements for pharmaceuticals as per ICH guidelines, Guided 21 graduate projects and 22 under graduate projects. He is a recipient of J.S.S. Memorial award for being the Best outgoing M.Pharm student, J.S.S. College of Pharmacy, Ootacamund, Recipient of Indian Pharmaceutical association award for getting 1st rank in M.Pharmacy and Recipient of Narinder Mohansood award for best outgoing student in Pharmaceutical Chemistry Specialisation, M. Pharmacy, J.S.S. College of Pharmacy, Ooty.

S.K. Agarwal

Vice President
Orchid Chemicals and Pharmaceuticals Limited
R&D Centre, Chennai

Dr. Agarwal has completed his M.Sc and Ph.D. in Organic Chemistry from Lucknow University. He did a certificate course in Radiation Safety from NIH, Bethesda, USA. He invovled in the Drug Discovery and Development Programmes specially structure based Molecular Designing, setting and Monitoring Milestones, Developing of Chemical Process Technology etc. He has a working experience in Government Research Institutes, foreign University and Pharmaceutical Companies. He has held several important posts in the management of projects, co-ordination of inter disciplinary team and computer skills.

Dr. Agarwal has 56 paper publications and has presented several papers in conference. He has filed 77 patent to his credit. He received several awards and honours he also the recipient of 'Wockhard's Significance Performance Award. He also holds important positions in several National and International Societies.

S.B. Katti

Division of Biopolymers
CDRI, Lucknow 226 001

Dr. S.B. Katti has completed his M.Pharm. from the University of Mysore (1975) and his Ph.D. from the same university in 1980. At present he working an Scientist F (Deputy Director) in the Medical Chemistry Division, CDRI, Lucknow. He did his Post-Doctroal Fellowship from the University of Zurich, Switzerland and has worked as Research Associate in the University of Chicago, USA. He has also visited Germany regarding INSA - DFG in 1994.

He has more than 50 publications in pear reviewed journals. His field of specialisation is in medical and Bio organic Chemistry and his areas of interest are Chemistry of Nucleic Acids, Peptides and protein DNA interaction. He has succeeded in attaining Indian patents two each of US and EU patents and presently is working on 1 US Patent.

Satya P. Gupta

Professor of Chemistry
Birla Institute of Technology and Science (BITS)
Pilani

Satya P. Gupta is a professor of Chemistry at Birla Institute of Technology and Science (BITS), Pilani. He obtained his M. Sc and D. Phil degrees from University of Allahabad, in 1967 and 1971, respectively. For his doctoral degree, he worked with Professor Bal Krishna in Quantum Chemistry, leading to the development of a new molecular orbital method, known as IOC-w-Technique (inclusion of overlap charges in w-technique). The method was found at that time very useful in dealing with the problems of p-electron systems. After his doctorate, Gupta spent a couple of years at Tata Institute of Fundamental Research (TIFR), Mumbai, working with Professor Girjesh Govil on the structure and functions of biomembranes. He joined BITS in 1973 and since then he has been there only, working on the theoretical aspects of drug design. He has made notable contributions in this area, for which he has been bestowed upon the Ranbaxy Research Foundation Award, a coveted national award, and made the Fellow of the National Academy of Sciences, India (F.N. A. Sc.). He is presently an advisory member of the Technical Resource Group on Research and Development on HIV/AIDS, constituted by Ministry of Health and Welfare, Government of India. He has acted as a Guest Editor of Current Medicinal Chemistry and is now the Editor-in-Chief of Current Medicinal Chemistry-Cardiovascular and Hematological Agents, both published by Bentham Science Publishers BV, The Netherlands and U.S.A.

Dr. Rakesh Kumar Sharma

Joint Director
Institute of Nuclear Medicine and Allied Sciences (INMAS)
Brig. SK Mazumdar Road, Delhi

Dr. Rakesh Kumar Sharma, M.Pharm, PGDBM (Project Management), Ph.D, is presently working as Scientist 'F' and Joint Director at INMAS, Delhi, and heading the Divisions of Radiopharmaceuticals, Biocybernetics and Radiation Biology. His current research interests include drug design, development of SPECT/PET radiopharmaceuticals for nuclear scintigraphy & therapy, and magnetopharmaceuticals for MRI, in vivo Magnetic Resonance Spectroscopy and radiation biology.

Dr. Sharma had been a visiting fellow at Institute of Biophysics (1991 and Institute of Biophysical Chemistry

(1992), University of Frankfurt, Frankfurt/M, Germany; Centre for Molecular Immunology, Havana, Cuba (2000); INSERM U-438, Grenoble, Cedex, France (2000); PET Centre, Central Clinic, Bad Berka, Germany (2000); University of Applied Sciences, Jena, Germany (2000); CIMAB SA, Havana, Cuba (2001) and KMC, Kettering, Ohio, USA (2002). He has also worked as Associate Professor at Max-Planck Institute for Biological Cybernetics at Tuebingen, Germany in 2002-03. He acclaimed the prestigious Young Scientist Award instituted by Brig. SK Mazumdar Memorial Trust for the year 1993 and Laboratory Scientist of the Year 2001 award. Besides guiding a group of scientists and research scholars, he is also spearheading active research collaborations with prestigious centers/hospitals in Germany, Cuba and Italy in the fields of PET, cancer therapy and radiopharmaceuticals for RAID, RAIT and for infection scintigraphy. He did pioneering work in the field of MRS of intact cells and mouse tumor model.

Dr. Rakesh Kumar Sharma is life member of several professional societies. Currently, he is Vic-President of IHPA. He has 3 patents and 81 publications and many popular articles to his credit besides contributing 13 chapters in books and editing two monographs.

He is the Chair-Elect of the Regulatory Sciences Section of the American Association of Pharmaceutical Scientists (AAPS). He is the current Chair of the Ocular Drug Delivery & Disposition focus group of AAPS. He is serving on the editorial board of Drug Delivery Technology and he is the one of the new editors of Clinical Research and Regulatory Affairs. He received his B.Pharm (Hons) from Birla Institute of Technology and Science, Pilani, M.Pharm (Pharm. Engg.) from Jadavpur University, Calcutta, and PhD from University of Southern California, Los Angeles, CA.

Uday B. Kompella

Associate Professor
Dept. of Pharm Sciences
986025, Nebraska, Medical Center
Omaha, NE 60195-6025-USA

Dr. Uday B. Kompella, PhD, is an Associate Professor of Pharmaceutics and Ophthalmology at the University of Nebraska Medical Center, Omaha, NE, USA. Dr. Kompella's research is focused on developing new drug and delivery approaches for treating disorders associated with elevated vascular endothelial growth factor expression. Dr. Kompella's research is currently funded by the National Institutes of Health and Pharmaceutical Industries. He has 50 publications in various international journals.

B. Pitchumani

Dept. of Chemical Engineering
IIT, Hauz Khas, New Delhi 16

Dr. B. Pitchumani is professor at Particle Science and Technology laboratory, chemical engineering department, IIT Delhi. He is editorial member of various international journals related to powder processing. He is also member of International and National Committees related to powder handling and pollution control.

His research interest area is powder size, shape measurements, estimation of flow properties of powders and retrofit existing powder storage system to minimize segregation and improve flowability of material. Research work has been carried for production of ultra fine particles and separation of fine particles from air solid system. High efficient dust collectors are developed after extensive research at laboratory. Many of the research work at IIT Delhi have been implemented in Industry.

Published 150 papers related to powder production by pulverizing, dust control and powder characterization. There is collaboration with various European universities in exchange of research information and mutual student exchange.

Ram B. Gupta

246, Ross
Dept. of Chemical Engineering
Auburn University, Auburn
AL-36849-5127, USA

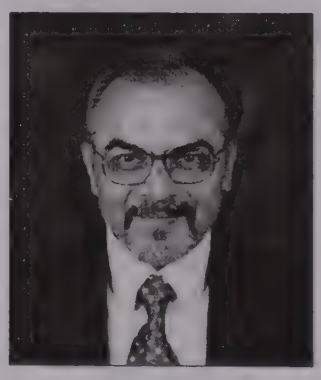
Dr. Gupta is an Associate Professor, Department of Chemical Engineering, Anburn University, Anburn, AL. He completed his Ph.D in 1993 at the University of Texas and did his Post-Doctoral Research at the University of California, Bakeley. He has been confered conferred with several National and International Awards. He has authored 3 books and has also hosted a website at the Auburn University which contain experimental data on solubility of various solutes in supercritial fluids. He has 8 patents to his credit. Dr. Gupta has availed several grants for his research projects. He has 40 publications in National and International Journals and has presented 52 papers in the conferences. He has been chairman and vice-chairman for several AICGE meetings from 1997 onwards. He has also been a reviewer for several international journals namely AICGE Journal, Journal of Physical Chemistry etc. Dr. Gupta's current research interest are nano technology and its application in nanomaterials, supercritical fluids, bioseparation, polymers, drug design and development of enviornmentally drug design and development of environmentally benign processes. Dr. Gupta has intilized teaching methodology in variety of courses of including chemical process safety, Graduate seminars, Energy Balance, Chemical Thermodynamics etc.

Moses S.S. Chow

Faculty of Medicine
Chinese University of Hong Kong
Shatin, NT, Hong Kong

Dr. Moses Chow, is Professor and Director of School of Pharmacy, The Chinese University of Hong Kong. Prior to his current appointment in Hong Kong, he was Professor of Clinical Pharmacy at the University of Connecticut and Director of Drug Information Service at Hartford Hospital. His current research interest includes pharmaockinetics, pharmacogenomics and the development of Chinese medicine. He has authored and co-authored over 200 articles in major pharmacological and pharmaceutical journals and written 8 book chapters and monographs. He has served as a visiting professor at 7 universities. He has been also active in many professional activities and organizations including the American College of Clinical Pharmacology (Previously Secretary, Board Member as well as Chairman of Annual Meeting), American Chinese Pharmaceutical Association (President 1999), American Society of Health-systems Pharmacists and American College of Clinical Pharmacy. He is currently elected as the first President of the Asian Association of Schools of Pharmacy. He has been a consultant to National Institute of Health (National Heart Lung and Blood Institute), 1996-2000 and the United States Pharmacopeia Convention, Inc. (Expert Review Panel on cardio-renal drugs), 2000-2005. He was Editor of Formulary, 1989-2001 and serves on editorial advisory boards of 6 pharmacology/medical journals.

N.K. Jain



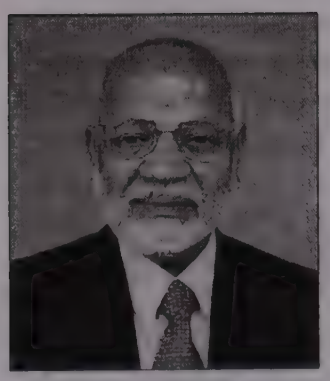
Professor, Department of
Pharmaceutical Sciences
Dr. H.S. Gour University
Sagar (M.P.)

Prof. Jain has completed his M.Pharm and Ph.D. from Sagar University, Sagar. He is an accomplished Teacher having taught at Nasik, Baroda, Indore, New Delhi, Sagar (India) and Dubai. He is also a Recipient of 'Teacher of the year' 2003 award of APTI. He has published over 250 research papers, review articles and other popular articles. He has authored several books in various fields of pharmaceuitcal sciences.

Prof. Jain has held several important positions. Some of them are : Referee : Indian Journal of Pharm. Sciences and Member of its Advisory Board; Indian Journal of National Products; Pharma Times; International Journal of Pharm. Excepients, International Journal of Pharmaceutics; STP

Pharma Sciences, President : Indian Pharmaceutical Association, M.P. Branch and Member, Central Executive Council Since '88-89, Nominated Member of All India Board of Pharma. Sciences, AICTE, New Delhi. Ex-Vice President, Indian Pharma. Association, Delhi Branch; Vice-president, APTI, '86-88, 91-93; Hon. Secretary, Indian Pharma. Association Vadodra Branch '82-86 and Editor, Bulletin of IPA Vadodra Branch, Ex-Head, Dept. of Pharma. Sciences, University of Sagar; Head, Dept. of Pharmacy, Delhi University Principal, College of Pharmacy, Delhi, Principal, College of Pharmacy, Nasik, Dean, Faculty of Technology, Chairman Board of Studies; Member Executive Council; Dean-in-charge, Faculty of Engineering, Dr. H.S. Gour University, Sagar, Visiting Professor, Dubai Pharmacy College, Dubai (UAE). He is only pharmacist in India with Ph.D. in pharmacy and Master's in Law. He in a life member of IPA, APTI, AMI, IHPA, ISTE, FIC and CRs. Professor Jain has successfully guided 15 Ph.D and 44 M.Pharm. candidates. He is credited to have completed 3 major research projects (UGC, CSIR, MHRD) and one book writing project is (UGC) in progress.

M.J. Nanjan



Director
TIFAC Core in Herbal Drugs &
PG and Research Studies
JSS College of Pharmacy
Ooty

Prof. M.J. Nanjan, Director, TIFAC Core in Herbal Drugs, PG studies and research is working in JSS College of Pharmacy, Ooty. He retired as General Manager and Director of R&D Centre, Hindustan Photo Films, Ootacamund. He also served as Prof. in Physical Chemistry at the University of Madras. He is a Principal Investigator of the Indo-German bilateral research project foundry on anti-cancer macromolecular targeting. He visited many foreign countries during his cancer as a

- Visiting Professor to the University of Koln, Germany, under German Academic Exchange Programme (DAAD).
- Visited USA, Canada, Germany, UK, France, Italy, Switzerland, Austria, Hollands, Denmark, Japan, Hong Kong, Thailand and Singapore and delivered invited lectures at Universities / Institutes of technologies on various topics in chemistry / polymer chemistry / emulsion science / drug delivery systems and interacted with several scientists / academicians.
- Visited Dupont's R&D Centre at Neussenberg and Agfa's Plant at Leverkusan, Germany and interacted with their experts.

He published 66 research papers in international and national journals guided 16 Ph.D. students and presently guiding 5 research students. His field of interest includes, polymers and their applications, Herbal formulations, Photographic Sciences and Technology.

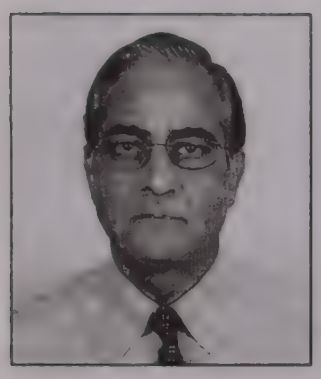
Shanta Mehrotra

Scientist-f, Deputy Director
Head, Pharmacognosy &
Ethnopharmacology Division
National Botanical Research
Institute, Rama Pratap Marg
Lucknow 226 001

Dr. Shanta Mehrotra, MSc from Lucknow University and Ph.D. from Kanpur University (1983) has over 32 years of research experience in medicinal plant research and is mainly engaged in herbal drug research particularly in standardization and quality evaluation of raw drugs and finished herbal products. She has published over 68 research papers and communicated 15 research papers in National and Inter-national Journals. Her division is now recognised by Dept. of ISM & H. Ministry of Health and Family Welfare, New Delhi as drug testing laboratory. The Ethnopharmacology Division in 2000 has helped to develop scientifically validated and standardised globally marketable herbal drugs, cosmaceuticals and nutraceuticals. She is also engaged in CSIR Inter-laboratory project for the development and commercialization of biodynamic compounds and in 3 NMITLI projects with the joint research work with other sister laboratories and other organizations.

Dr. Shanta M is a recipient of National Award for Women Development initiated by DST for the year 2003 and has undertaken projects of DST, DBT, ISM 4 H, ICMR, NMITRI, etc. She has served as consultant to WHO She has two patents to her credit and field fire patents.

M.K. Raina



203, Rainbow Appartment
Powai, Mumbai 400 072

Dr. M.K. Raina has a doctorate degree in pharmacy (Pharmacognosy) with over 34 years experience in Medicinal Plants (R&D). His contributions to the pharmaceutical industry includes setting up of R & D centre at Ranbaxy Lab. Ltd, Dabur Research Foundation, Lupin Labs Ltd, etc. He is a consultant / advisor for several Ayurvedic companies with regard to standardization of medicinal plants, new product development and quality control.

He was the international consultant for UNIDO (UNDP), Vienna and has undertaken projects and completed at Vietnam, Malavi, Uganda and Nigeria. He was also an international consultant for IUCN, Switzerland and Veve Group, Albania. Till date he is the member of Ayurvedic Pharmacopocia Committee, Ministry of Health, Govt. of India.

He was invited a guest speaker at several national and international conferences. He is also a member of the editorial board of several indexed journals.

Ludwig Huber

Compliance Fellow
Agilent Technologies

Ludwig Huber, Ph.D., is worldwide Fellow at Agilent Technologies. He is the author of the books "Validation and Qualification in analytical Laboratories", "Validation of Computerized Analytical and Networked Systems", Interpharm and of the "Network Quality Package" and "FDA Inspections Package" from Labcompliance. He is the editor of www.labcompliance.com, the global on-line resources for validation and compliance issues for laboratories and compliance. He was a team and review member of PDA's task forces "21 CFR Part 11" and "Validation of Laboratory Data Acquisition Systems", and of the GAMP special interest group on Laboratory Equipment. Currently he is on the Scientific Advisory board of the European Compliance Academy and a member of IVT's task force on Network Infrastructure Qualification.

B.G. Nagavi

Principal
JSS College of Pharmacy
Mysore

Graduated from Govt. College of Pharmacy, Bangalore. He obtained his post-graduation & PhD from Birla Institute of Technology & Sciences, Pilani. He has long time experience of about 23 years in teaching, research & administration. He has 50 research publications to his credit both in National & International Journals. He has attended World Pharmacy Congress in Jerusalem, held in 1996. He has organized national conferences & AICTE – sponsored faculty Development programmes. He has authored 5 books. He is serving as President of IPA, Mysore branch, Chairman, Hospital Pharmacy Division of IPA, Editor, Indian Journal of Pharmaceutical Education (IJPE) and Syndicate member of Rajiv Gandhi University of Health Sciences, Bangalore. He was awarded SE Wright travel fellowship of University of Sydney in the year 1992, UGC travel assistance in the year 1994, Repatriation General Hospital (RGH), Adelaide Fellowship in the year 1996. Dr. Nagavi – attended first Asian Pharmacy Educators meet (APEM) in Thailand in 2000. His research areas of interest include Pharmacy Practice, Biopharmaceutics & Pharmacokinetics, Microcrystalline cellulose, pharmaceutical analysis and Pharmacy Act. In November 1999, APTI Conferred, the distinguished Teacher Award (1998-99) and in Dec 2001, IPA conferred fellowship for his contributions to the profession of pharmacy. Currently Dr. Nagavi is Vice- President of IPA, Chairman of Hospital Pharmacy Division and Vice-President of Karnataka State Pharmacy Council.

Samsinah Hussain

Associate Professor
Department of Pharmacy
University of Malaysia

Dr. S. Hussain has completed his Bachelor of Pharmacy, Honars from the University of Malaysia and Doctor of Philosophy (Physiology) from University of Leads, U.K. He has been appointed as Committee Member for Pharmacy Board Training section, Ministry of Health, Malaysia.

He held the post of Chairman of UM Pharmacy Programme Accrediation Committee. He has been appointed by the Ministry of Health as member of Drug Control Authority (DCA) and Pharmacy Board.

He has served in the project evaluation panel for National Biotechnology programme and was also appointed as an expert in the panel for strategic Research Project, advistory in the panel for clearing house for tobacco control and interview in the panel of National Science Fellowship Research Scholarship and Post-graduate scholarship, HRD programme all for the Ministry of Science and Technology, Malaysia.

Dilip G Shah

Chief Executive
Indian Pharmaceutical Alliance
Vision Consultancy
201, Darvesh Chambers
743, PD Hinduja Road, Khar West
Mumbai 400 052

Mr. Dilip G Shah, CEO of Vision Consulting Group, a firm specialized in strategic planning, has 37 years' varied experience in the pharmaceutical industry.

In addition, he currently holds the following positions: Member of the Management Board of the International Generic Pharmaceutical Alliaqnce (IGPA), Secretary-General of the Indian Pharmaceutical Alliance (IPA), an Association of 10 large research based national companies. Together they share 30 percent of the domestic market, account for one-third of exports and contribute 90 percent of R&D spending in the pharmaceutical industry, Member, The World Bank Generics Consultative Group, Co-chairman of the FICCI's Committee on Pharmaceuticals, Member of the CII's Committee on Pharmaceuticals., Member of the Boards of Advisors of : Express Pharma Pulse, Pharmabiz.com, Journal of Generic Medicines, U.K., Member of the Advisory Panel for the Business Briefing: Pharma Generics, U.K., Member of the Board of Directors of Emcure Pharmaceuticals Limited and Zuventus Healthcare Limited. Author of the first book on "Drug Pricing in India" and occasional contributor to business press, he graduated from the premier business school in India, Indian Institute of Management (IIM), Ahmedabad and has been a guest faculty for their Management Development Programmes.

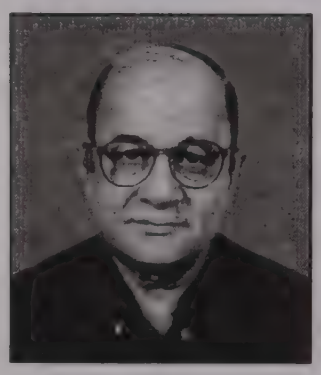
Karin Nyfort-Hansen

Clinical Pharmacist
Repatriation General Hospital
Adelaide, South Australia

Karin Nyfort-Hansen is a clinical pharmacist at the Repatriation General Hospital, Adelaide, South Australia, where she has worked since 1981. She has been involved in both drug distribution and clinical pharmacy services, and since 1999 has provided clinical services to the hospital's respiratory, orthopedic and rehabilitation units. She contributes to the hospital's pulmonary rehabilitation program and is an Adjunct Clinical Associate of the University of South Australia, where she lectures to undergraduate and postgraduate pharmacy students. In 1997 Karin spent six months in India assisting the establishment of clinical pharmacy education and practice at the JSS Colleges of Pharmacy in Mysore and Ooty. She gained certification in geriatric pharmacy in 2000. Karin's clinical interests include respiratory medicine, psychotherapeutics, anticoagulation and medication safety. She writes regularly on developments in respiratory

pharmacotherapeutics for the Journal of Pharmacy Practice and Research. She continues to have a keen and active interest in the development of clinical pharmacy practice in India, and is a co-editor of the textbook Clinical Pharmacy Practice: Essential Concepts and Skills.

C.J. Shishoo



8, Shivalaya
Gulbhai Tekra
Ahmedabad 380 006

Associated in various capacities with L.M. College of Pharmacy, Ahmedabad, for more than 33 years, Dr. C. J. Shishoo has retired as Principal, Head and Professor, Dept. of Pharmaceutical Chemistry, in 1997. He got his Master's degree in Pharmaceutical Chemistry in 1963 from the University of Iowa (USA) and got his Ph.D. in Pharmaceutical Chemistry from Gujarat University in 1976.

He has been working for more than 30 years in the field of Pyrimidine and condensed pyrimidine chemistry and has developed a very simple and facile methods to synthesize pyrimidines and condensed pyrimidines.

Recently, his fundamental work on the interaction of rifampicin and isoniazid reaching implications to the bioavailability of fixed dose combination of rifampicin and isoniazid has attracted world wide attention. More recently he has become interested in developing in vitro-in vivo correlations and mathematical models to predict bioavailability of drug formulations. He has published more than 70 original scientific papers in reputed National and International journals. He has also co-authored several reviews and holds several patents.

Dr. Shishoo is a member of American Chemical Society, member - Medicinal Chemistry Division and member- Organic Chemistry Division.

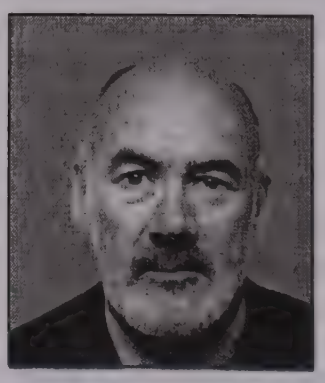
After retirement from the college in 1997, he has been associated with consumer movement in India as a Trustee and as Advisor to the Compound Testing Laboratory of Consumer Education and Research Centre (CERC), Ahmedabad. He is a member of Advisory Committee of SRISTI.

George K. John

School of Pharmacy
Faculty of Health Sciences
Potche-f-stroom University
South Africa

Dr. George K. John obtained his M.Pharmacy from Potchefstroom University, South Africa. Presently he is undergoing doctoral programme on Pharmco-economics in Potchefstroom University, South Africa. He is also working as a lecturer at School of Pharmacy, University of Potchefstroom. He is experienced as hospital pharmacist, Pharmacy Technician, Medical representative and product specialist. He has presented several papers and attended seveal conferences at national and international level. Dr. John is a member of pharmaceutical society of South Africa. He is a consultant for the South African National Department of Health on public health and pharmaceutical policies. His areas of interest include corporate management, strategic planning, marketing, pharmacoeconomics, Drug Utilization Review and Primary Health.

David Cosh



9, Smith Darrien Street
Netherby
South Australia - 5062

David Cosh graduated in pharmacy from the University of Adelaide in 1966. He has since obtained his Master of Applied Science from the University of South Australia, and is a Fellow of both the Pharmaceutical Society of Australia (PSA) and the Society of Hospital Pharmacists of Australia (SHPA). In 1996 he qualified as a Board Certified Pharmacotherapy Specialist under the auspices of the American Pharmaceutical Association and is a member of the Australian Association of Consultant Pharmacy.

He practised as a clinical pharmacist at Repatriation General Hospital (RGH) Daw Park in Adelaide South Australia from 1981 to 1999.

He has held a position as Adjunct Senior Lecturer at the School of Pharmaceutical, Molecular and Biomedical Sciences, University of South Australia and has lectured in both undergraduate and postgraduate pharmacy programs for over 20 years. He currently serves as a reviewer for the Annals of Pharmacotherapy and writes for Drug Scan in the Australian Journal of Pharmacy Practice and is a member of the Gastroenterology writing group for Therapeutic Guidelines; an Australian organization that produce practice guidelines for a number of clinical specialties.

He has visited India on four occasions since 1997 to both teach and support clinical pharmacy practice at JSS institutions and hospitals in Ootacamund and Mysore and will do so again in December 2003.

He has served as the national education co-ordinator for the SHPA and works with the PSA and the Australian College of Pharmacy Practice to provide clinical education for practising pharmacists in South Australia.

Thomas Einarson

Associate Professor
Faculty of Pharmacy
University of Tornto
Canada

Dr. Thomas Einarson holds two masters degree in 'Master of Science and Master of Education' and Ph.D. in Pharmacy Administration all from the University of Arizona. Currently he is working as Associate Professor, in the Faculty of Pharmacy, University of Toronto. He is also serving the Department of Pediatrics Hospital for sick children and Department of Health Policy, Faculty of Medicine, University of Toronto.

He is chairman of the pharmacoepidemiology section of the Editorial Advisory, Board of Annuals of Pharmacotherapy and Co-Chairman of the International Congress of Pharmacoepidemiology in Toronto.

His research interests are for the Development and application of quantitative methods to drugs and drug use, including pharmacoepidemiology, drug utilization, pharmacoeconomics, meta-analysis, and literature analysis. Dr. Thomas Einarson has to his credit 156 Peer reveiwed articles, 25 book chapters, 99 abstracts and 131 posters.

Bruno Louis

Senior Clinical Pharmacists
Co-ordinator Pharmacy
Information System
Department of Pharmacy
Al Khod, Muscat, Oamn

Mr. Louis completed his M.Pharm from Punjab University, Chandigarh in 1978. He has guided M.Pharm and MD students and has done research work in Drug utilization studies. He has several publications to his credit and has presented several research papers in national and international conferences. The present research activities include drug utilization studies and pharmacokinetics. He is an editor of Pharmline - A professional pharmaceutical journl published from Kerala. He is an expert in evaluation and implementation of pharmacy Information systems and visited Bangkok General Hospital, Bangkok, Thailand and Alfred Luthli Hosptial, Durban, South Africa.

Stefan Kowalshi

Senior Clinical Pharmacists
Co-ordinator Pharmacy
Information System
Department of Pharmacy
Al Khod, Muscat, Oamn

Stefan Kowalski is currently a Senior Lecturer in Clinical Pharmacy at the School of Pharmaceutical, Molecular and Biomedical Sciences at the University of South Australia and as a clinical pharmacist at the Repatriation General Hospital, Daw Park, South Australia. His current clinical involvement at

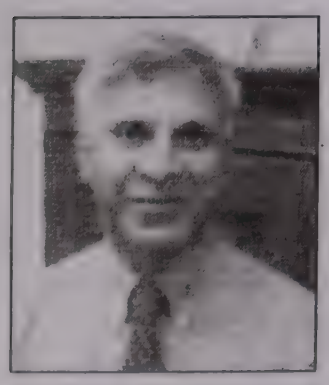
the Repatriation General Hospital is with Aged and Extended Care patients. He completed a Bachelor of Pharmacy Degree in 1980 and a Masters in Applied Science in 1988. He has worked as a Hospital Pharmacist in several Australian hospitals and has obtained certification with the US commission for Certification in Geriatric Pharmacy. He is currently program coordinator for the University of South Australia's post graduate Clinical Pharmacy programs.

Praful R. Naik

President
Bilcare Limited
307, Narayan Peth
Pune 411 030

P.K. Nair obtained M.Pharm., Ph.D. from Institute of Technology, Banaras Hindu University, Varanasi. He served as Technical Services Manager, Ethicon, Ahmedabad, General Manager of Product Development and Formulation Division of Smithkline Beecham Pharmaceuticals, Bangalore and Cadila Pharmaceuticals, Ahmedabad. Currently he is the President, Bilcare Limited, Pune. He is also a visiting faculty of Al-Ameen College of Pharmacy and Annamalai University. He underwent several management training programs in India and specialised technical training in several countries. He has presented several paper in national and international level.

Iqbal Ramzan



Associate Professor
(Pharmaceutics & Anaesthesia)
Associate Dean
(Admissions & Administration)
Faculty of Pharmacy
The University of Sydney
NSW 2006, Australia

Dr Iqbal Ramzan obtained his undergraduate degree in Pharmacy in New Zealand and his post-graduate training from the Department of Pharmacy at the University of Sydney where he obtained his MSc and PhD degrees specialising in Drug Pharmacokinetics and Pharmacodynamics. Dr Ramzan spent five years at the State University of New York at Buffalo in the Department of Pharmaceutics where he carried out postdoctoral training under the guidance of Distinguished Professor Gerhard Levy. He also held Faculty appointment at the same institution and also was Assistant Professor of Pharmaceutical Sciences at the School of Pharmacy at the University of Pittsburgh. Dr Ramzan returned to Australia in 1989 where he has held academic positions as Lecturer and Senior Lecturer at the University of Sydney. In 2002 Dr Ramzan was promoted to the rank of Associate Professor in the Faculty of Pharmacy at the University of Sydney where he also holds a conjoint appointment as Associate Professor of Anaesthesia. Dr Ramzan is author/co-author of over 90 research papers in the area of drug assay, pharmacokinetics and pharmacodynamics. In 2000 Dr Ramzan was appointed an Associate Dean in the Faculty of Pharmacy, University of Sydney, with responsibility for Admissions and other U/G Program matters. Dr Ramzan is a registered pharmacist.

D.R. Krishna

Professor
Drug Metabolism and Clinical Pharmacokinetics Lab
University College of Pharmaceutical Sciences
Kakatiya University
Warangal, Andhra Pradesh

D.R. Krishna is Professor in Pharmaceutical Sciences, College of Pharmaceutical Sciences, Kakatiya University, Warangal, India. He is a recepient of several Post Doctoral Fellowships from Germany. He is an expert on Preclinical Pharmacokinetic Studies, In vitro- In vivo metabolism studies, anticancer screening and in the design and formulation of newer drug delivery systems. He has supervised the Ph.D. work of 9 students and 12 M.Pharm students. He has been awarded more than 10 millions in grant money from various funding agencies. He is a member of the advisory board and reviewer of several journals. He is a proud recepient of Prof.M.L. Shroff Gold Medal for securing highest percentage of marks in B.Pharm. He has co-authored a text book on Clinical Pharmacokinetics along with U.Klotz. He has over 85 research publications and 35 presentations.

P.C. Dandiya

Retd. Professor of Pharmacology
SMS Medical College
Jaipur

Dr. P.C. Dandiya, Ph.D. from Toronto in the 1959, is presently the Emeritus Professor and Advisor to Dr. Robert Helieg Library, S.M.S. Medical College, Jaipur. He is specialised in Psychoneuro-pharmacology and was elected the fellow of inter-national college of pyscho-neuro-pharmacologist as a recognition of his research work. He received the sigular honour of being elected a fellow of Indian Academy of Medical Sciences.

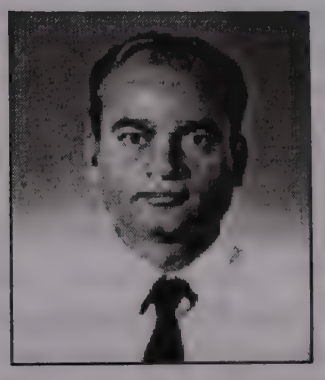
Dr. P.C. Dandiya has published over 170 papers and 14 books and was invited to write "Pharmacological Research in India by the annual review of pharmacology, 1974. He has held several prestigious positions in India like President - PCI, President - IPC, President - Indian Pharmacology Society in the years 1976, 1981 and 1987 respectively. he was conferred with the shakuntala Amir Chend Prize by the Indian Council of Medical Research and the Prof. M.C. Shroff memorial Award by Ind. Hospital Pharmacists Association. He was also honoured by the Indian Pharmaceutical Association with the Eminent Pharmacist Award and the Life Time Achievement award by the Association of Pharmaceutical Teachers of India.

Ruth I Ferguson

Specialist Pharmacist
Dunedin Hospital
Dunedin, New Zealand

Ruth Ferguson registered as a pharmacist in New Zealand in 1974. She worked in hospital pharmacy in New Zealand and United Kingdom before studying for a MSc in Clinical Pharmacy and PhD at Strathclyde University, Glasgow. After working as a post-doctoral research fellow she returned to New Zealand. She has since worked in academic teaching roles in clinical pharmacy, in drug utilization research, medicines assessment for registration and in adverse reactions monitoring. She is currently employed in Dunedin Hospital, Dunedin, New Zealand as specialist pharmacist in cardiology and renal medicine and teaches in the National School of Pharmacy, Otago University. Travel has enabled Ruth to work for short periods in Accra, Ghana and in Mysore and Ootacamund, India.

G.J. Rao



Department of Physiology
School of Medical Sciences
University Sains, Malaysia

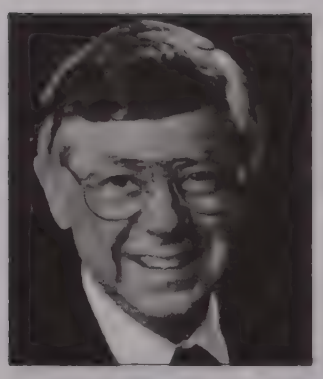
Dr. Rao has completed his MBBS from Andhra University, M.D. from Mysore University and Ph.D. from Mangalore University. He was felicitated with many awards through out his academic curriculum which includes the merit schorship award, Distinguished Alumini Award, Letter of Appreciation from I.C.M.R., New Delhi as an Expert Advisor and the Excellent Service Award from the School of Medical Sciences, USM, Malaysia. He was also the recipient of Best Research Presentations Award.

In Rao has an academic working experience of 30 years. He has an updated knowledge of Clinical Physiology and has delivered several lectures in Post-Graduate Training Programmes and CME of Clinical Specialities. He is also incharge of Clinical services at Pulmonary Function Clinic.

His research interest lies in investigation of 2,3 - Dig levels, effect of broncho-dilators, anti-edema, histamine and gluco carticoid in surfact system of lung, funded by University Sains, Malaysia. Simultaneous by he is also studying the effect of indomethacin and Nabomethine on renal function. He has 13 publication to his credit at national and international levels.

He is a member of Journal Board of Indian Journal of Medical Research and Reviewer for the Journal 'Arogya'. He has served the public at Manipal by organising Health Exhibitions, Fund Raising for poor patients and delivering guests lectures on Respiratory problems in asthamatics.

John Alfred Bell



President
Common Wealth Pharmaceutical Association
4, Carnarvon Road
Reseville, NSW 2069
Australia

John Bell is Immediate Past President of the Commonwealth Pharmaceutical Association, an organization representing 43 national pharmacy organizations throughout the Commonwealth of Nations. He was President of the Pharmaceutical Society of Australia from 1987-1988 and President of the Australian College of Pharmacy Practice from 1996 – 1998. John is now Principal Advisor to Pharmacy Self Care, a consumer health information program managed by the Pharmaceutical Society of Australia.

He has been awarded Fellowships of the Pharmaceutical Society of Australia, the Royal Pharmaceutical Society of Great Britain, and the Australian College of Pharmacy Practice. In 1990 he was awarded the Federation of Asian Pharmaceutical Association's award for services to community pharmacy. John was made a Member of the Order of Australia in 1993. In recent years, on behalf of the Commonwealth Pharmaceutical Association, he has been a member of delegations to Bangladesh, Ghana, Jamaica, Tanzania, Trinidad & Tobago, Zimbabwe and Zambia to consider and make recommendations on matters relating to pharmacy practice and public health. Since 1969 John has been the proprietor/manager of a community pharmacy in Sydney which provides specialist services to nursing homes, hostels and private hospitals.

S.R. Sarvadekar

Chief Pharmacy Services
Grand Medical College
Sir J.J. Hospital
Mumbai 400 008

Dr. Suresh Saravdekar did his post graduation in Pharmacology and Doctorate in Medical Pharmacology from Bombay Unviersity. He has 17 years of experience as Chief Hospital Pharmacy Services in Public Health Care System of Ministry of Health, State of Maharastra. He is responsible for standaradisation and specification, computation of requirements, finalisation of tenders and rate contracts, registration of manufacturers, procurement of medical supplies for all state run medical colleges and supplies. His areas of interest include enhancement of status and image of hospital pharmacist, public awareness and sensitization of patients as regards proper use of medicines and promotion ofrational use of drugs. He has several research papers published in different journals of pharmacology. He holds several professional memberships.

Motoko Kanke

Professor of Pharmacy
Kyoritsu College of Pharmacy
1-5-30 Shibakoel
Minato-Ku
Tokyo 105-8572, Japan

Motoko Kanke is Professor of Clinical Pharmacy at the Kyoritsu University of Pharmacy, Tokyo, Japan, where she has taught since 1995. Prior to this position she was Professor of Pharmaceutics and Clinical Pharmacy at Fukuyama Unviersity, Faculty of Pharmacy, Hiroshima, Japan, for 11 years. In addition, from 1979 through 1985 she participated as a senior scientist in the United States in the Pharmaceutics Division of the University of Kentucky, College of Pharmacy where her research focused on novel drug delivery systems. She has several patents to her credit including a US patent related to biodegradable microspheres as drug carriers in both injectable and oral dosage forms.

At present, she directs the clinical pharmacy program in the graduate program where she developed and instituted a study-abroad curriculum for his students. Every year these students are placed in several university medical centers throughout the US of from 4 to 10 weeks to introduce them to the globalization of pharmaceutical care as they round out their experience in becoming clinical pharmacists in Japan. Her pioneer work in establishing the clinical pharmacy program at Fukuyama and Kyoritsu is nationally recognized and in 2001 she was awarded the first Outstanding Educator Award from the Association of Private Pharmaceutical Shools of Japan.

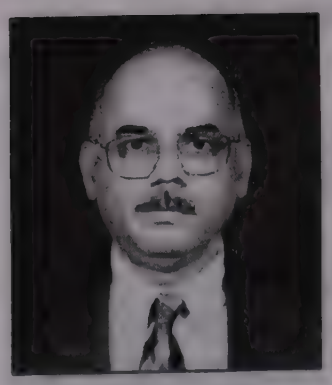
M.S. Nagarsenkar

Department of Pharmaceutics
Bombay College of Pharmacy
Mumbai 400 098

Dr. M.S. Nagarsenkar is professor and HoD in the Dept. of Pharmaceutics. She has 25 years research experience. Her research interests are in the areas of Liposomal drug delivery systems, oral controlled release dosage forms, bioavailability studies, improved formulations of conventional dosage forms cd specialized emulsion systems.

Dr. Nagarsenkar has thirty four research papers to her credit in National and International Journals. She has presented 37 papers in various National and International Conferences. Her accomplishments also include one Indian patest in the year 2003. She has authored book chapters in Biopharmaceutics and Pharmacokinetics, hospital and clinical pharmacy. She is also a member of IPA, Controlled Release Society and APTI.

Rajagopal Thiruvengadam



Director (works)
M/s. Tablets (India) Limited
Chennai

Rajagopal Thiruvengadan is a pharmacy graduate from Madras Medical College and Master Degree in Business Administration from the university of Madras. He is associated with the Pharma Industry for the last 30 years. During his career, he was associated with small medium and large companies like Astra IDL, Sandoz, Mical etc., in various capacities like Analytical Chemist, Microbiologist, Quality Control Manager and Works Manager.

Associated with M/s. Tablets (India) Limited, Chennai since 1984, a leading Manufacture of Amino Acids based formulations - in various capacities as Quality Control Manager, Works Manager and presently as Director (works). During his career, he has traveled to japan, Switzerland, Germany, Italy, Singapore, Colombo, Philippines, Malaysia, Vietnam and Bangkok on various Techno-Commercial assignments, During his travel to Japan and Switzerland he had the orientation in production and G.M.P. at M/s. Roussel Morishita Pharmaceuticals Plants at Kotobuki Pharmaceutical Company Limited, Japan and recently at M/s. Toa Pharmaceutical Plant, Japan.

As an active member of Indian Pharmaceutical Association he served as Joint Secretary, Treasurer, Secretary, Vice President and President of Tamil Nadu Branch of Indian Pharmaceutical Association. He was associated with 38th I.P.C. as Chairman for registration Committee, with 48th I.P.C., as Joint secretary of the Local organizing Committee.

Indian Pharmaceutical Association awarded him the fellow ship award during the I.P.C. at Indore in 1999 for his dedicated service to the profession of Pharmacy. 'The Pharmacist of the Year 2001' Indian Pharmaceutical Association, Tamil Nadu branch conferred him 'The Pharmacist of the year 2002'.

Richard Streamer

Asia-Pacific Regional Manager
Foss NIRS Systems
USA

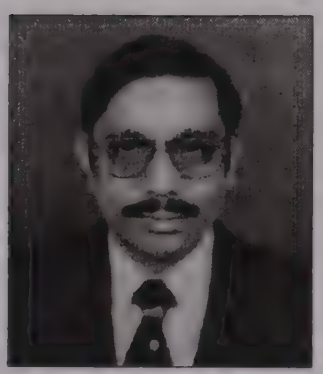
Richard Streamer is the Asia-Pacific Regional Manager for Foss NIRSystems, a U.S. based manufacturer of Near Infrared Spectroscopic products and world leader in the application of the technology in the pharamaceutical, chemical, petrochemical and other industries. Richard is based in Australia where Foss NIRSystems has its regional support office for the Asia-Pacific area.

Richard has extensive experience in the application of Near Infrared Spectroscopy in industrial fields and has installed and implemented hundreds of Near Infrared solutions throughout the Asia-Pacific region. He is the

member of the task force for defining NIR implementation in regulatory protocols .He is associated closely with various regulatory bodies around the world , in implementation of NIR technologies both on –line and laborotory environments.

Richard has been in his current position for 16 years and prior to that has worked in other analytical supply companies after graduating with a BAppSc from the University of Technology in Sydney and Graduate Diploma in Environmental Studies from Macquarie University. Richard has also undertaken numerous courses in sales and marketing for his role in Foss NIRSystems.

S. Veerramani



Founder & Chairman
Fourtts (India) Laboratories Pvt. Ltd.
Chennai

Mr. S. Veerramani has completed his post graduate degree in Management (M.B.A. in Marketing). He was the Founder and Chairman of FOURTTS (India) Laboratories Pvt. Ltd., Chennai and is presently working in the same pharmaceutical industry. He is the Vice-President of Indian Drug Manufacturers Association, Mumbai. He was the former Chairman of Indian Drugs Manufacturers Association (Tamil Nadu State Board) for two consecutive terms.

Nityanand S. Shenoy

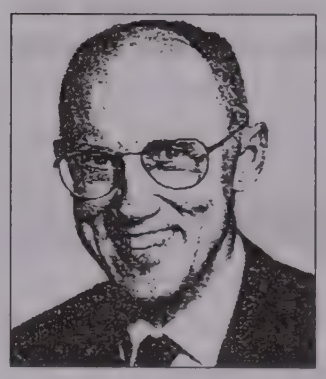
Vice-President
Marketing
PRS Permacel Private Limited
63, Bombay Samachar Marg
Fort, Mumbai 400 001

Mr. Nityanand S. Shenoy is a Bachelor of Technology (Mechanical Engineering) and holds an MBA (Marketing) from the Indian Institute of Management, Bangalore. After spending a few years with Mico-Bosch and the Godrej Group, in India, he joined the Permacel division of Johnson & Johnson (India) in 1990 as Product Manager responsible for their innovative labeling business. In 1999, Johnson & Johnson Limited chose to quit its industrial product business in India and concentrate exclusively on its health care business. The local partner of Johnson & Johnson in India, the PRS Group took over the management of the company, which got rechristened as "PRS Permacel Private Limited". The label business of PRS Permacel has a strong focus in security labeling and Mr. Shenoy was responsible for the growth of this business in India.

PRS Permacel today is actively involved in the business of Brand Protection and has a committed sales, marketing and R&D team dedicated to this business. Mr. Shenoy today is the Business Head for "KAVACH" - PRS Permacel's 'Brand Protection Franchise', in addition to his position as the overall Marketing Head of PRS Permacel.

Mr. Shenoy in his capacity has presented many papers in the area of Brand Protection in various countries across the world.

Peter Kielghast



President
Federation International
Pharmaceutique (FIP)
The Hague, The Netherlands

Peter J Kielgast was born on May 14th, 1945. He finished his degree M.Sc. (Pharm) in 1969. He has worked as Officer in The National Board of Health, Drug Section during the year 1969-73, Secretary in the Danish Pharmaceutical Association (Danmarks Apotekerforening (DA) from the period 1973 -77, in 1973 he was a member of the Executive Committee of the Pharmaceutical Group of the European Union, in 1975 - LLM (Master of Law), 1977 - Head of the Department in DA, 1978 - 94 Director General of DA, 1984 -86 Vice Pesident of the Pharmaceutical Group of the European Union, 1986-94 Professional Secretary for the Communicty Pharmacy Section of The International Pharmaceutical Federation (FIP), 1987-89 President of the Pharmaceutucal Group of the

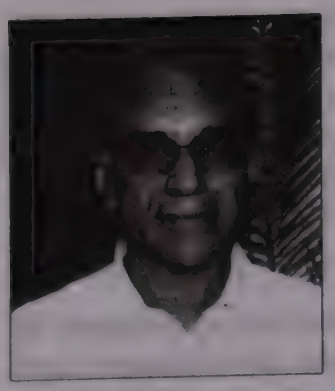
European Union, 1989 -94 Member of the Board of Directors, Peptech Europe Ltd., Copenhagen, 1992-94 Member of the Board of Directos, Nomeco Ltd, Copenhagen, 1992-94 Member of the Board of Directos, Hafslund Nycomed Ltd., Oslo, Norway, 1994 Proprietor Pharmacist, Taastrup Pharmacy, Denmark, 1994-98 Chairman of FIP's Board of Pharmaceutical Practice and in 1998 President of FIP.

T. Ilango

Registrar
Tamilnadu State Pharmacy Council
Chennai

He is currently the Registrar of the Tamil Nadu State Pharmacy Council, Chennai. After completing his B.Pharm he was Associate in Institution of Chemist. He is the Founder President of IPGA West Zone and South Zone. Along with Mr. M M Yusuff (Drug Inspector), he translated Drugs and Cosmetics Act 1940 to Tamil which was published by Chemists and Druggist Association. He helped revise the pay scales with equal status to B.E. and B.Sc. during 1983. He was a Drug Inspector from 1974 to 1996.

R. Srinivasan



Member
Community Pharmacy Division IPA
and Chairman CPD of IPA
Tamil Nadu Branch

He is a member of Community Pharmacy Division, Indian Pharmaceutical Association and Chairman CPD of IPA, Tamil Nadu Branch. He is also the trustee, AIOCD Educational Trust, Editor-Journal of Community Pharmacy & PharmaLink, Chairman of Pharmacy Practice Committee of 55th Indian Pharmaceutical Congress, Chennai

Umesh V. Banakar

Banakar Consulting Services, 10251, Tammar Drive
Carmel, IN 46032, USA

He received his Bachelor of Pharmacy degree from Bombay University, Bombay, India in 1978 and Ph.D. from Duquesne University, Pittsburgh, Pennsylvania, USA in 1985. He joined Creighton University, School of Pharmacy & Allied Health in 1985 as an Assistant Professor and was promoted to Associate Professor in 1988. He joined St. Louis College of Pharmacy in 1990. Since 1997 through 1999, he was professor of Pharmaceutics and Chairman of Pharmaceutical Sciences and Graduate Program at Butler University, College of Pharmacy & Health Sciences in Indianapolis.

He has authored over 100 publications, over 100 published abstracts and presentations, numerous specialized workshop manuals, several chapters and monographs, over 45 expert book reviews and 5 guest editorials. He is the co-author of an electronic text: Basic Pharmacokinetics. He is on the roster of experts with WHO, United Nations – TOKTEN program and International Executive Service Corps (IESC). He is listed in Who's Who in Biotechnology, Who's Who Among Asian Americans, and American Men and Women of Science. In 1997, he won the nomination for the distinguished Fulbright Scholar Award for Lecturing. He has received numerous awards for excellence in teaching, faculty development and achievement in research and scholarly activity and he is the recipient of two Service to Country Awards presented by IESC. He is the founding Editor-in-Chief of International Journal of Pharmaceutical Advances and is a referee for 8 other major pharmaceutical journals. He has offered numerous national and international symposia and workshops on design, development and evaluation of conventional and advanced/specialized pharmaceutical products. He has successfully executed and completed over 150 clinical studies (Phase I, II and III including BE) for several pharmaceutical products for submission to numerous regulatory agencies worldwide including the US-FDA and Western Europe.

Furthermore, he has planned and executed the development, both in vitro and clinical, of over several NDAs and ANDAs.

Olivia M Limuaco

Dean, School of Pharmacy
Centro Escolar University, Manila, Philippines

Olivia M Limuaco a registeed pharmacist holder of MS Pharmacy and Ph.D. Sci.Ed. currently the Dean of the School of Pharmacy and Professor for both undergraduate and post graduate of Centro Escolar University, Manila, Philippines.

CEU is one of the 36 schools offering pharmacy course and has the biggest enrolment, top provider of licensed pharmacist, ISO 9001:2000 certified and granted full autonomy by Commission on Higher Education (CHED)

Dr. Limuaco is a member of the CHED Technical Committee on Pharmacy Education, Executive Vice President of the Philippine Pharmaceutical Association, President of the Association of Colleges of Pharmacy, the secretary general of Federation of Asian Pharmaceutical Association, and the Program Chair & Director of Asian Association of Schools of Pharmacy. She is actively involved in the revision of policies and standards for pharmacy education, drafting of the new code of ethics for pharmacists, new pharmacy law of 2003 and providing continuing education for practising pharmacists and academician.

Simon Bell

Simon completed his Bachelor of Pharmacy degree at The University of Sydney in 2000 and registered as a pharmacist in 2001. Simon is now into his second year of a PhD project developing and evaluating new and extended roles for pharmacists in the health care system.

Simon has been involved with the International Pharmaceutical Students' Federation (IPSF) for several years, firstly as the inaugural secretary of the Asia Pacific Regional Office and subsequently the chairperson. Most recently Simon was elected IPSF President for 2003-4 at the IPSF World Congress in Singapore. During his term as president Simon is living and working at the IPSF head office in The Hague, The Netherlands.

Simon is a member of the Pharmaceutical Society of Australia (NSW Branch) Futures Taskforce, the Immediate Past President of the NSW Young Pharmacists and a practicing community pharmacist.

Sunil S. Jambhekar

Associate Professor of Pharmaceutics
Department of Pharmaceutical Sciences
Massachusetts College of Pharmacy/HS
179 Longwood Avenue, Boston, MA 02115

Sunil S. Jambhekar, a native of Ahmedabad, Gujarat, obtained his B. Pharm. degree from L. M. College of Pharmacy, Gujarat University, in India. After working for four years in pharmaceutical industry in India, he joined the graduate program in Pharmaceutics at the University of Nebraska in the United States, where he completed his M.S. and Ph. D. degrees in Pharmaceutics. He then joined the faculty of the School of Pharmacy at the Massachusetts College of Pharmacy in 1982, as an Assistant Professor of Pharmaceutics. At present, he is an Associate Professor.

Dr. Jambhekar teaches two Pharmacokinetics courses to professional pharmacy (PharmD) students and Advanced Pharmacokinetics course to graduate students. Additionally, he teaches Advanced Physical Pharmacy I and II and Unit Operation courses to graduate students. He is actively involved in directing and supervising research of graduate students at master's and doctoral levels. Over the years at the Massachusetts College of Pharmacy and Health Sciences, he has directed research of seven doctoral students and twelve master's degree students. As a result, Dr. Jambhekar has authored or coauthored about seventy scientific presentations at national meetings and international conferences, twenty four publications and others are in preparations, and ten book chapters. In addition to his own graduate students, Dr. Jambhekar has served on the advisory committee of several graduate students in Pharmaceutics and the Chemistry disciplines. He has reviewed scientific books and research articles for professional journals such as the Journal of Pharmaceutical Sciences, International Journal of Pharmaceutics, American Journal of Pharmaceutical Education, Pharmaceutical Technology, and International Journal of Compounding. Dr. Jambhekar has been an invited external examiner, to participate in the oral qualifying examination of doctoral graduate students, at Northeastern University College of Pharmacy and as an external examiner at St. John's University and Halifax University, colleges of pharmacy, and Sri Ramchandra Medical College and Research Institute (Deemed University) in Chennai, India.

Dr. Jambhekar's research interests include applications of physical chemical principles in the development and evaluation of immediate and controlled release dosage forms, applications of co-processd cyclodextrins as diluents, applications of cyclodextrins for improving the dissolution and stability of drugs, In Vitro and In Vivo correlations,

and. He is a member of various professional organizations. Dr. Jambhekar is a recipient of several awards at his college which include teacher of the award, advisor of the award, and scholarly publication award. In 1993-94, he was awarded Fulbright scholarship in lecture/research category for India.

Manidanna Venkateshwaralu

Deputy Drugs Controller (I)
C.D.S.C.O. West Zone, CGHS Dispensary Building Ist Floor
Antop Hill, (DITS), Mumbai 400 037

Dr. Venkateswarlu completed his Ph.d. in Pharmaceutical Sciences in April 2000 from Andhra University, Waltair, Visakhapatnam. He is presenting working as Deputy Drugs Controller (India), Central Drugs Standard Control Organization, West Zone, Mumbai with additional charge of Assistant Drugs Controller (India), Mumbai Port, Mumbai till February 2001, having overall change of Western Region and responsible for uniform implementation of the provisions of the Drugs and Cosmetics Act and Rules thereunder related to manufacture and import of drugs and incharge Dy. Drugs Controller (India) Drugs Inspector Training Scheme.

He has several articles published in IDMA Bulletin, Express Pharma Pulse, Pharmabiz, Heritage Healing, AAIPS and AIDCOC. He has several achievements to his credit as Drug Inspector. In appreciation of sincere and outstanding work in the Drugs Control administration he was conferred the Best Drug Control Officer Award in Year 2001 by the All India Drug Control Officer's Confederation, Mumbai. He also won the Eminent Pharmacist Award in the Year 2001 in appreciation of Services to the Regulatory Affairs by the Indian Pharmaceutical Association (IPA) Hyderabad.

Vinod P. Shah

Senior Scientist, USFDA, USA

Dr. Shah is a Senior Research Scientist in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). He received his Pharmacy degree from Madras University, India and Ph. D. in Pharmaceutical Chemistry from the University of California, San Francisco (UCSF). After serving as a postdoctoral fellow with Dr. Sidney Riegelman at UCSF (1970-1975), Dr. Shah joined FDA in 1975. Since joining the agency, he has served in different capacities in CDER/FDA. He is a recipient of several CDER/FDA awards for Leadership Excellence, Team Excellence and Excellence in Communication, FDA's Award of Merit, Commendable Service Award and Scientific Achievement Award.

Dr. Shah is author/co-author of more than 180 scientific publications and co-editor of two books. Dr. Shah has developed Regulatory Guidelines for the pharmaceutical industry in the areas of (1) Dissolution Testing of Immediate Release Solid Oral Dosage Forms (2) In Vitro - In Vivo Correlation (3) Scale-Up and Post Approval Changes - Semisolid (SUPAC-SS) (4) Topical Dermatological Drug Products: Bioavailability and Bioequivalence (5) Bioanalytical Method Validation (6) General Bioavailability / Bioequivalence for Orally Administered Drug Products and (7) Biopharmaceutics Classification System. Dr. Shah is an expert member of the International Federation of Pharmaceutics (FIP)/Board of Pharmaceutical Sciences and Chair of Special Interest Group on Bioavailability and Bioequivalence. Dr. Shah is a recipient of FIP/Industrial Pharmacy Section Medal Award. Dr. Shah is an Adjunct Professor, College of Pharmacy at University of Kentucky, Lexington, KY.

Dr. Shah is a sustaining member and Fellow of American Association of Pharmaceutical Scientists (AAPS). Dr. Shah has planned, developed and organized more than 30 AAPS/FDA co-sponsored scientific workshops to address complex and regulatory scientific issues, and has prepared reports which have served as a global reference article and/or used by the FDA and other regulatory agencies in developing guidances. He is a recipient of AAPS Presidential Citation and AAPS Distinguished Service Award. He is elected as President of AAPS for 2003.

B. Prabha Shankar

Mr. B. Prabha Shankar has been working in the Pharmaceutical industry for the past 20 years and has very wide experience in International Pharmaceutical Marketing, Product Management, Regulatory Affairs, In Licensing, Out Licensing, Custom Synthesis, Clinical Trials and Bio-Equivalence Study Projects.

He is a postgraduate in Pharmaceutical Sciences with Specialization in Pharmacology from Andhra University, Waltair. He has done postgraduate Diploma in Business Management from British Institutes, Mumbai and had the opportunity of getting a job abroad immediately after completing M.Pharm.

After working as Pharmacist for a year he joined Eurodrug Laboratories, Holland in 1983 and worked till 1997 as Country Manager based in Sultanate of Oman. During his tenure in Sultanate of Oman, he had the opportunity to

work in close co-ordination on Regulatory Affairs with various Multinational Companies of Holland, Belgium, Germany, Switzerland, Finland, Canada, U.S.A. and India. He had been attending the Marketing and Scientific Conferences of Eurodrug Laboratories every year since 1983 in Asia pacific Countries.

Mr.B.Prabha Shankar moved to India in 1998 to take up a challenging job as Country Manager, Eurodrug Laboratories Division India.

He is a Member of Royal Society of Health, London and Consultant for Modern Medicine of France. He was awarded a title "Dragon of Eurodrug" in serving the organization for more than 15 years. He is a Life member of Economic Committee of Andhra Pradesh and Exhibition Society, Hyderabad. He is a permanent invitee to the Central Executive Committee of Indian Pharmaceutical Association (2002-2004).

In 1999 established Kakatiya University Pharma Alumni Association Hyderabad (KUPAAH) and since then organized State & National level events like 2nd National Pharmacy Students Convention, Pharma Rallies, Scientific Seminars, Quiz, Debate Competitions, Free Health Check-up camps, . Workshops for Teachers, Students and Community Pharmacists in co-ordination with IPA Education Division and IPA State & Local Branches in AP. He has been giving guest lectures on Pharmacology topics to the students and has keen interest on students activities. He is presently doing Ph.D. in Biotechnology.

Sindhchai Keokitichai

Dean, Faculty of Pharmacy
Silpakorn University, Thailand

Dr. Sindhchai Keokitichai completed his Ph.D. in the United Kingdom during 1975-80. Presently he is the Dean of Faculty of Pharmacy, Silpakorn University. His research interests include enzymology and Enzyme Kinetics, investigation and development of antineoplastic agents from natural sources, analysis of Thai Traditional Medicines and Formulations from ancient Inscriptions and Cost Accounting System and its implimentation, concerning Education and Health Services in Particular. He served as the Vice-President for Planning and Development as well as Provest, Silpakorn University, for two years during 1997-1999. He is presently the Chairman of Pharmaceutical Education Consortium of Thailand.

Ramagopal V. Mudumbi

Associate Director
Glaxosmith Kline, King of Prussia, PA

Dr. Mudumbi completed his Ph.D (Cardiovascular Pharmacology) in 1982 from Post-graduate Institute of Medical Education and Research, Chandigarh, India. He is presently working as Associate Director, Glaxo Smithkline, King of Prussia, PA. He has extensive technical, managerial and leadership experience in clinical (Phases II -IV) and pre-clinical studies focussing on team - oriented drug development and drug safety evaluation. He has broad research expertise in (Both in academic and pharmaceutical industry) in Molecular Biology, Pharmacology and Toxicology.

Dr. Mudumbi has published more than 20 papers in peer reviewed US and international scientific journals. He has presented more than 30 papers in various US and international meetings and publised the presentations as abstracts in various scientific journals. As a special recognition for research activity his biographical profile finds place in Marquis American Men and women of science (19th edition), who's who in science and engineering (3rd edition), who's who in technology (1994 edition).

Sujith J. Chandy

Reader, Department of Pharmacology & Clinical Pharmacology,
CMC Hospital, Tamil Nadu, India 632 004

He completed his MBBS & MD with specialization in Pharmacology & Clinical Pharmacology. He has been teaching undergraduate and postgraduate students at CMC Hospital, Vellore. He has been carrying our Research in the areas of drug use in hospitals, applied kinetics, medical education. Currently involved in 2 externally funded projects of INCLEN and WHO. He is involved in Clinical and Hospital Pharmacy and Administrative set up of the hospital. He has publication in the areas of Problem Based pharmacotherapy, TDM and Pharmacoepidemiology.

Others Speakers

P. Bindra
Vice-President, Ranbaxy Laboratories, New Delhi

S.K. Kulkarni
University Institute of Pharm. Sci.
Panjab University, Chandigarh

S.W. Deshpande
Secretary General, AIDCOC, Mumbai

A.K. Dasgupta
Lambda Laboratories, Sarkej-Gandhinagar Highway
Bodakdev, Ahmedabad 380 054

Neeraj Saxena
Director, TIFAC Centre
Department of Science & Technology
Technology Bhavan, New mehrauli Road
New Delhi 110 016

A. Sivathanu Pillai
Distinguished Scientist and
Chief Controller of Research & Development
Defence Research & Development Organisation (DRDO)
New Delhi

Ajit Dangi
Director General
Organisation of Pharmaceutical Produers of India
G K Marg, Peninsula Corporate Park
Mumbai 400 013

G.J. Samathanam
Director / Sc.F
Department of Science & Technology
Technology Bhavan, New Mehrauli Road
New Delhi 110 016

G. Padmanabhan
Director / Scientist F
International Scientist Corporation Division
Dept. of Science & Technology, Technology Bhavan
New Mehrauli Road, New Delhi 110 016

Arun Ramanathan
Secretary to Government of Tamilnadu
Chennai

S. Ramakumar
Chairman, Bio-informatics Center, IISC, Bangalore

Batu Andrade
Joint Secretary, West Zone, AIOCD, Mumbai

R R Shah
Mercury Laboratories, Vadodara

R. Sabapathy
Medopharma, Chennai

Re-scripting Pharma Marketing in the Post-Patent Era

Gauri Chaudhari
Head, Strategic Planning Consultant, FCB - Ulka Health Care

1997, IPR (Intellectual Property Right) bill was passed in the parliament and the world changed for the Indian pharmaceutical industry....literally.

As per the new bill, by 2005, the Indian pharma companies will need to strictly adhere to the new product patent law. After 2005 we will not be allowed to market the formulations patented by other company.

Initially, the pharma companies believed that the only answer to IPR is increasing R&D investment and inventing new molecules.

Fortunately this is not the only way.

In the post patent scenario a pharma company can reach the newer heights by focussing on the manufacturing, marketing or distribution functions. IPR has thrown up several opportunities to the Indian manufacturers. In the end, the winner will be the one who taps it the best.

This session attempts to uncover the marketing challenges / opportunities of the post-patent era.

Traditionally pharma companies believed in pushing the brands in the markets by wooing doctors or luring chemists. The new era will demand very different skills, practices, attitudes and more importantly the mindsets. The answers will largely depend on which of the following routes one takes.

The Indian pharma companies are not known for their marketing expertise. But this should not deter them from learning them. There could be a big reward at the end of the journey.

***Co –marketing** : Post patent era will witness several co-marketing agreements. The companies that are not adequately represented in the country will seek such arrangements. Co-marketing practices will be very different from the regular practices of selling branded formulations. This kind of promotion will require employment of newer techniques. DTC, e- selling, support groups will be at the core of such marketing.*

***OTC (Over The counter drugs)**: Today the OTC market in India is around Rs 6000 crs growing with double digits. OTC market is expected to boom in the next decade. Increasing level of education, higher level of health consciousness and increased comfort with self -decision are the reasons behind the boom.*

OTC marketing requires very different skills, different infrastructure but over and above it needs extremely different mindset.

***NDDS (Novel Drug delivery Systems)**: Developing and selling NDDS will open up new avenues in the market. But which of the NDDS will be successful in the market will largely depend on the patients' preference for that NDDS.*

***Looking outside India** : Much is being talked about the 'Generic opportunity' in USA .Several pharma giants are gearing up to market Generics in western countries in a big way.*

Demand for herbal and ayurvedic formulations is increasing globally.

India has traditional expertise in his area. Indian brands of herbal origin can conquer the globe. All it will need is courage to dream big and know-how to realize it.

So which of the above is the most ideal way? How can one exploit these opportunities? What should one be prepared for before jumping into any of these areas?

The objective of the session is to answer some of these questions and understand pharma marketing of post patent era.

Rational Drug Use and Evidence Based Medicine

Karin Nyfort Hansen
Clinical Pharmacist, Repatriation General Hospital
Adelaide, South Australia

The goal of rational drug use is to provide patients with the most appropriate, safe and cost-effective drug therapy. Achieving this in practice is a challenge due to the wide range of factors that influence prescribing decisions. In recent years evidence based medicine has become an

important new influential partner for pharmacists promoting rational drug use. Evidence based medicine (EBM) refers to the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. Over the last ten years EBM has become integrated into routine medical practice in many western countries, and is now an important influence on prescribing. Both the benefits and risks associated with drug therapy can now be quantified in ways which are of relevance to individual patients.

The factors that have supported the rise of EBM such as the increasing complexity of health care, rising costs, the internet and health care consumerism are now also apparent in India. In order to use EBM to promote rational drug use, pharmacists need to develop skills in literature retrieval, critical appraisal, and biostatistics. They also need to be able to communicate research evidence on drug therapy in a clinically relevant, balanced and succinct way. Pharmacists with these skills will find that their opinions and advice are eagerly sought whenever prescribers are uncertain about drug therapy choices.

Process Validation Pharma and Bulk products

B.G. Kini
B-401, Shantiswarup, NP Thakkar Marg
Vileparle-East, Mumbai 400 057

Definition : *Establishing the documented evidence which provides a high degree of assurance that a specific process will consistently produce a product of predetermined specification and quality attributes.*

Where did the validation come from? Why should we perform the validation ? What are its benefits? How far we do we have to go? These are the few questions asked.

Validation is performed to assure the quality, regulatory requirement, reduce the cost and now it is a law in many countries. It is specifically referred to in EU Directives and EU GMP. It is a requirement according to CFR. and ICH Q& guidelines. It is a basic principle of GMP.

Validation Master file : *Mainly includes scheduling of various validation programs and its implementation before starting any manufacturing activity.*

Validation Policy : *The company's overall policy, intentions and approach to the validation including: process validation, cleaning validation, analytical method validation, in-process control and test procedures, computerized systems, documentation of each validation phases, persons responsible for design, approval and review.*

Different stages of Validation : *Establish User Requirement Specification, Installation Qualification, Factory acceptance testing, Operation Qualification, Performance Qualification.*

Calibration of various gauges used in the process and utility and testing equipment.

Preparation of protocol, Process Validation (optimization and validation): number of validation runs, batches selected, critical quality attributes, critical process parameters, sampling plans, specifications and testing procedures, acceptance criteria

Report preparation, compliance to acceptance criteria

Review : *Incorporation of validation conclusion in the process documents.*

Other related issues : *Change controls: Formal evaluation of the potential impact of planned modifications on the validated status of product, process or facility.*

To provide mechanisms for ongoing process optimization and ensure a continuing state of process control.

Prevent unauthorized modification to a validated system. Evaluate proposed changes against development and technology transfer documents

Determine the impact of changes on critical chemical and physical properties of the product.

Ensure the utility is validated : *Control on raw materials (only approved vendor materials are used)*

Training of technical staff and operators: SOPs, Operation of equipment, Checking environment, filling of documents, signing , checking of Bill of materials, Dispensing, Evaluation of training and periodic training

Approach to the validation : Prospective, concurrent and retrospective validation

Revalidation : Change in equipment, Process, location, materials and any change in the process which can change the quality and therapeutic value of the dose

Many of the details could not be included which will be covered at the time of presentation. A copy of the presentation will be forwarded to u if u wish.

Would like to present the program on 19th Dec at 10 AM. Alternatively it can be arranged on 18th Dec, afternoon at 3pm.

Memory Enhancing And Antiamnesic Agents From Natural Source

Professor S.K. Kulkarni
University Institute of Pharmaceutical Sciences
Panjab University, Chandigarh 160 014

Alzheimer's disease (AD) is a progressive neurodegenerative disease that results in impaired memory, thinking, and behavior. It is the most common cause of dementia in the elderly and affects large population globally, a problem of an ageing society. People with AD experience gradual memory loss as well as impaired judgment, difficulty in concentrating, loss of language skills, personality changes, and a decline in the ability to learn new tasks. The exact causes of AD although not entirely known, abnormal plaques and proteins (b-Amyloid) deposition in the brain, degenerative brain changes, loss of cholinergic neurons and other chemical messengers due to excitotoxicity and, oxidative stress are reported to be the cause. A genetic link has also been associated. The free radicals (highly reactive molecules that can cause oxidation, or damage to cells) play an important role in the development of AD. There is no specific treatment available for AD, but studies suggest that medications, herbs and supplements, and lifestyle adjustments may all help to slow the progression and improve the symptoms of the disease. Drugs used for the treatment of Alzheimer's include tacrine, donepezil, Rivastigmine, Estrogen and NSAIDs (Ibuprofen, naproxen, indomethacin, meclophenamate). A number of plant-derived drugs have been used in the Indian system of medicine for long for enhancing learning and memory. These include Bramhi, aswagandha, Acorus calamus, Jatamansi, Shankapushpi, Amla, Gingko biloba, quercetin, Ginseng etc. Brahmi is, although one of the constituents of many herbal preparations used as 'brain tonic' for improving memory, concentration and learning, there is a need for development of mechanistic based herbal preparations for the treatment of Alzheimer's and related disorders. Herbal preparations, individually or in combination are known to offer neuroprotection against age related oxidative changes leading to learning and memory deficits.

"Good Storage Practices for Pharmaceutical Products: Need for action in India"

Dr. D. B. Anantha Narayana
Managing Trustee
Delhi Pharmaceutical Trust, New Delhi

Ever Since the Pharmaceutical industry and trade grew in India; there has been some awareness about the proper storage aspects of API's and Pharma products. However it did not receive right attention except at the Manufacturing premises, probably driven by regulatory compliance needs. Starting from the planning of stores, cold rooms etc and monitoring of their performances great discussion and action could be seen in most producing firms. However what happened after the API's/Pharma products left the Manufacturer's premises did not receive the right attention. While the manufacturers did precious little to ensure that their products are stored properly all through the chain till the products reached the consumers, the participants in the rest of the chain, namely the transporters, whole sale distributors, retail chemists were more oblivious of the need for proper storage as long as products were at their premises. Majority of the latter were not aware of the requirements and their responsibilities, a few who knew the same took umbrage that it costs a lot to do so and never bothered.

The language used by the manufacturers on the labels were more to meet the law as they understood and no one bothered to review the text matter used to indicate storage conditions. The Indian Pharmacopoeia gave guidelines in the para under "Storage" under General Notices. Most Pharma Product Development used to stick to these texts while drafting the text for labels and cartons

regarding storage conditions. These texts were neither Pharmacist friendly nor consumer friendly.

A survey conducted in 2002 by the Delhi Pharmaceutical Trust (DPT), brought out for the first time in India hard data on the pathetic situation in this area, needing urgent action. This survey confirmed that " it is the obvious things that one neglects most often" The DPT later worked and brought out a" Good Storage Practices (GSP"s) for Pharmaceutical Products at a Retail Pharmacy", a guide for retail pharmacists. It is also a fact that WHO Has brought out recently GSP"s covering the entire area once the products leave the manufacturers premises and till it reaches the consumer.

In the last few months, several happenings including the Cadbury chocolates issue and actions by Drug Controllers of few states have brought to light the actions emanating in this area. All aspects of the issue would be dealt in the Invited talk.

Supercritical Fluid Technology for Respiratory Drug Delivery Systems

Uday B. Kompella
UNMC College of Pharmacy
986025 Nebraska Medical Center, Omaha, NE 68198-6025.

Supercritical fluids (SCFs) are substances at their critical temperature and pressure. These fluids exhibit liquid-like densities and gas-like diffusivities and viscosities. SCF processes are offering versatile and efficient engineering of particulate drug delivery systems with reduced residual organic solvent content. The objective of our research is to develop drug delivery systems for budesonide using supercritical fluid technology. Our previous investigations indicated that budesonide reduces the expression of vascular endothelial growth factor (VEGF) and multidrug resistance associated protein-1, factors implicated in the tumor progression and chemotherapeutic drug resistance, respectively. Thus, budesonide drug delivery systems are of potential value in treating lung cancer and other VEGF related disorders. In this study, we prepared budesonide-PLA particulate delivery systems and budesonide-hydroxypropyl-b-cyclodextrin complexes using supercritical fluid processes employing SC CO_2 and assessed them both in vitro and in vivo. The budesonide-PLA particles were prepared using a PCA process, wherein the drug and polymer dissolved in methylene chloride were sprayed into supercritical CO_2. The particles formed exhibited a negative zeta-potential, mean particle size of ~500 nm, sustained in vitro release during a one month study, and reduced residual organic solvent content. To prepare budesonide-HPBCD inclusion complexes in solid state, budesonide and HPBCD mixtures were exposed to supercritical CO_2 for 20 hours. The inclusion complexes exhibited reduced drug crystallinity as evidenced by differential scanning calorimetry and powder X-ray diffraction analysis. FTIR studies suggested an interaction between the carbonyl group of budesonide and the hydroxyl groups of HPBCD. The dissolution rates were 2- to 3- fold higher for the SC CO_2 treated preparations compared to the untreated physical mixtures. Following intratracheal instillation of budesonide-HPBCD solution, budesonide suspension, and budesonide-PLA particle suspension in a mouse model, drug levels declined drastically with both solution and plain drug suspension formulations. With the microparticle formulation on the other hand, drug levels were higher on day 7, consistent with an infusion-type response. Thus, budesonide-HPBCD complexes and budesonide-PLA particles can be prepared with SC CO_2 processes and these systems provide immediate- and sustained- delivery, respectively, in the lungs.

Pharmacoepidemiology and the Pharmacist

Sujith J. Chandy
Reader
Department of Pharmacology & Clinical Pharmacology
CMC Hospital, Vellore Tamil Nadu, India 632 004

What is pharmacoepidemiology?

Pharmacoepidemiology involves the application of epidemiological principles and methods to study drug outcomes. A pharmacoepidemiologist assesses drug use and the resulting beneficial and unintended outcomes in large populations, often in the post marketing phase of drug use.

What is the purpose of pharmacoepidemiology?

The purpose of pharmacoepidemiology is to identify and quantify drug outcomes along with incidence rates and relative risk estimates. Drug outcome probabilities represent

the foundations for medical decision making and economic analysis.

What are the types of studies ?

Pharmacoepidemiologic studies are not limited to safety studies, but include all observational studies that describe the use and effects of pharmaceuticals in the real world setting.

Career Challenge & Preparation:

Pharmacoepidemiology allows the pharmacist to use clinical skills to identify and define therapeutic problems at the patient level, to investigate these problems at the population level, and to translate the findings as a basis for clinical decision making. Basic required skills include statistics and epidemiological methods; secondary skills include database management and psychometrics.

Role of the pharmacist

Applying the philosophy of pharmaceutical care to the use of drugs by society as a whole requires that pharmacists ensure that drugs are used safely, effectively, rationally and economically to meet the health needs of society. An extension to that would require that pharmacists also play a part in doing research into the use of the drugs they are giving to the patient

One of the prime roles of the pharmacist would be to do a Drug Use Evaluation (DUE) or Drug Utilization Review (DUR). Drug Use Evaluation is used in hospital and community settings to assess the appropriate use of particular drugs, evaluate the clinical effectiveness of drugs, monitor the impact of education and other intervention programs, and compare the costs of two or more drugs that are viewed as potentially interchangeable.

There are various other studies in which the pharmacist can also play a prominent role.

Impact on health policy

In order to impact on the health policy , a great deal of day to day research needs to be done on the prescribing and use of drugs. Pharmacists who are the medical professionals in day to day contact with drugs, doctors and patients are in an ideal position to do this research. Significant findings can then be translated into policy changes. Thus the role of the pharmacist in pharmacoepidemiology will be fulfilling and important on in the near future.

It is for the community of pharmacists to rise up to this challenge.

Continuous Cell Line – New Screening Model for Oral Mucosal Drug Delivery

Moses Sing Sum Chow
School of Pharmacy, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China

Despite of the advantages of oral mucosal drug delivery such as easy accessibility, rapid absorption and high bioavailability, the number of drugs which have been developed for oral mucosal delivery is very limited. One of the limitations in the development of oral mucosal delivery is the lack of a good model for in-vitro screening to identify drugs suitable for such administration. The availability of in-vitro cell lines, TR146 (derived from human buccal carcinoma) and HO-1u-1 (derived from floor of the mouth epithelial carcinoma) offer a new screening capability. The validation and characteristics of TR146 cell line and its utility in studying various beta-blockers have been published previously. Our unpublished pilot work on HO-1-u-1 indicated that this cell line when grown on cell culture inserts, produced features that are useful for studying drug permeability. Our preliminary results on beta-blockers confirmed this. Based on the differences and similarities between the TR146 and HO-1-u-1 cell lines, the TR146 cell line may be considered a suitable model for buccal permeability screening and HO-1-u-1 cell line for sublingual permeability screening. With further work, these cell-lines may help to identify many drugs suitable for both buccal and sublingual delivery in the future.

Accreditation of clinical pharmacy practitioners for community practice – attaining and maintaining competence

David Cosh
Education Co-ordinator
Pharmaceutical Society of Australia (South Australia)

Medication review, in residential care and the home, is an area of practice that is increasing in popularity in Australia. Accreditation to conduct medication

review is required for payment to be made for this non-supply related professional service and there are two bodies that can accredit pharmacists to practice – The Australian Association of Consultant Pharmacy and the Society of Hospital Pharmacists of Australia. Educating pharmacists to a level where they can both attain and maintain suitable clinical skills is a challenge for professional pharmacy organizations that are active in encouraging pharmacists to embrace these new services as a way of promoting quality use of medicines.

In 2004, the Pharmacy Board of South Australia will link statutory registration for any element of pharmacy practice to a designated minimum level of ongoing continuing professional development. Without current registration the operation of a community pharmacy is not be allowed so that failure to meet the minimum standards of ongoing education will have a direct impact on livelihood.

The Pharmaceutical Society of Australia and other organizations providing continuing education for pharmacists are being called upon to broaden their educational offerings to allow for all pharmacists to choose continuing education activities that best meet their own particular needs. This has relevance for pharmacists conducting medication review where the standards of practice are constantly being evaluated by medical practitioners and where failure to ensure clinical competence will see government reluctant to continue to fund these services. As Indian clinical pharmacy, with its birth in hospital practice, extends its services into the community the same challenges that confront both practitioners and those charged with ongoing education and the maintenance of standards in Australian practice will arise.

Pharmacoepidemiology and Health Policy: Issues for India

Thomas R. Einarson
Faculty of Pharmacy, University of Toronto

Pharmacoepidemiology is a field of scientific enquiry that involves the application of the methods of epidemiology to the study of drug use. Two many areas of study are pharmacovigilance and drug utilization studies. The former examines adverse effects of drugs, qualifying and quantifying them and identifying risk factors. The latter examine the effectiveness of drugs in real life situations and are able to identify new therapeutic uses for drugs. Observational generate extremely useful data in situations where randomized controlled trials cannot be used. They also provide long term follow-up and data that are not available in clinical trials.

The population of India is growing rapidly. At the same time, the economy is growing and the level of education is rising. Consequently, the standard of living is increasing. As people become more affluent, they take more drugs. With huge numbers of people doing so, it is inevitable that there will be many adverse reactions occurring in this population. At the same time, drug interactions will occur, some of which will be negative and others positive.

India has a great opportunity to integrate pharmacoepidemiology into its healthcare system. By observing and reporting events that occur, both positive and negative, it has the potential to become the world's largest human laboratory. Such information is largely unavailable in the world.

Policy makers must not ignore pharmacoepidemiology and its potential as the healthcare system evolves. Incorporation of its principles can generate data to serve the public. Pharmacists can play a major role, since they are already actively playing a role that focuses on drugs and drug use.

Drugs affecting surfactant system of lung

Dr. G.J. Rao, Malaysia
Department of Physiology, School of Medical Sciences
University Sains, Malaysia

The existence of surface tension forces of alveoli was discovered by Von Neergard in 1929. He has also speculated the presence of a surface active material (surfactant) acting against these surface tension forces, otherwise the lungs would collapse. However, extraction of lung surfactant was done for the first time by Clements in 1957 after a surprising lapse of nearly 30 years. In 1959, Avery and Mead reported collapse of alveoli in hyaline membrane disease due to deficiency of surfactant in the lungs. High surface tension pulmonary edema

induced by Nieman and Bredenberg and by the author and coworkers provided experimental proof on the additional role of surfactant in the prevention of pulmonary edema. Further, it was also observed that babies with hyaline membrane disease were more susceptible to infections and a possible immunological function by the surfactant was suggested.

Pulmonary surfactant that is secreted by Type II cells of alveolar lining is a lipoprotein. The lipids are mainly phospholipids, the predominant being dipalmitoylphosphatidylcholine (DPPC). The lipids lower the surface tension thereby preventing collapse of alveoli and pulmonary edema. Four types of surfactant proteins been identified. They are designated as SP-A, SP-B, SP-C and SP-D. SP-B and SP-C are essential in the formation of a stable lipid film at air liquid interface of alveoli. SP-A and SP-D do not seem to have a major role in surface tension lowering property except that SP-A helps SP-B in the formation of lipid film but they have immunological function.

Studies on pharmacological agents affecting surfactant system of lung started ever since the deficiency of pulmonary surfactant in hyaline membrane disease was reported by Avery and Mead. Cortisol and Thyroxine were found to be essential for the maturation of fetal surfactant system. Thus, antenatal administration of dexamethasone and antepartum adminstration of glucocorticoids in premature infants was tried in the prevention of hyaline membrane disease. Even with the advent of exogenous surfactant it is still in vogue. Where as estrogens were found to increase the surfactant secretion, testosterone and insulin were found to inhibit the secretion. Beta-adrenergic agonists increased surfactant release into the alveoli. Beta adrenergic agonists that were used as bronchodilators were known to relieve the respiratory distress due to their action on bronchial smooth muscle. Release of surfactants from Type II cells is a hitherto unknown additional action of bronchodilators by which the relief is obtained. The author and coworkers compared the relative efficacy of the adrenergic drugs used in bronchial asthma in terms of the surface tension values of bronchoalveolar lavage (BAL) fluid after their administration.

Experiments conducted in the author's laboratory using other pharmacological agents led to many other interesting observations. Screening of drugs used in edema revealed that surface tension values of BAL fluid were least after administration of frusemide. This may be the rationale behind frusemide being effective in refractory cases of pulmonary edema. Further, though glucocorticoids were found to be essential in the maturation of surfactant system in fetal lungs, administration of therapeutically equivalent doses in adult animals led to an acute decrease of DPCC in BAL fluid. A cautious administration of corticosteroids especially in larger doses as is done in ARDS may be needed till these adverse effects are ruled out in studies in adult human beings. Studies with histamine have shown that histamine administration decreases lecithin release in to the BAL fluid. It is proved to be H2 receptor mediated. Thus, surfactant deficiency may be one of the pathogenic factors in allergic lung diseases and pulmonary effects of other allergic diseases. A re-look at treatment strategies in these diseases may be needed when once the findings are confirmed in human studies. The findings with histamine are in contrast to the findings in culture on Type II cells emphasizing the fact that in vitro and in vivo effects may be different in view of the complexity of responses in the whole animal / individual.

Pulmonary surfactant is proved to have an immunological function Thus, surfactant deficiency may lead to respiratory infection / susceptibility to infection in cases like asthmatics. Studies are progressing in author's laboratory to observe the effect of exposure to pesticides on different components of surfactant system of lung. A deficiency may make farmers more susceptible to infections. With the exploration of the relative importance of each of the components of this natural surfactant in it's various functions, there is a vast scope for further research to observe the effects of commonly used pharmacological agents on the surfactant system of lung. In addition, there may be a demand for varieties of preparations of exogenous surfactant to suit individual needs. Thus, there is a promising future for pharmaceutical companies involved / interested in promoting research in this field. The plenary lecture will focus on all the above aspects.

Special Techniques in Formulation Design and Quality Control

Paul W. S. Heng
Head, Department of Pharmacy
Associate Professor in Pharmaceutics
National University of Singapore

In pharmaceutical formulation design, it is desirable that formulations are simple, optimized, reproducible and stable. For a formulator, predictor tools are extremely

helpful to reduce the workload and remove some of the drudgery of repeating many similar experiments. However, there are many constraints to a formulation and these can contribute to the complexities in formulation work. The formula may be dependent on commercial and production factors in addition to concerns associated with the active ingredient(s), route of administration and purpose of the dosage form. Intelligent software-based product formulation systems have been developed but the use of software predictions in formulation work are not without limits. Nevertheless, intelligent software packages can help to improve the efficiency of product development cycles once they are adequately "taught". On the formulator's bench, besides the issue of the ideal formulation, ingredients used will need to be characterized. It is increasingly important that physical characterizations of ingredients used for formulation or pre-formulation studies are carried out to ensure that the quality of ingredients as well as the bioactive agents are consistent and within specifications. This will ensure a smooth production run and consistent quality of the end products. As most pharmaceutical products marketed are oral solid dosage forms, it is inevitable that more research and resources are directed at the area of solid dosage forms. Many useful techniques had been developed to determine the physical properties of particles including roughness, flow, moisture sorption and powder rheology among others. These techniques will provide the means to differentiate and ascertain the quality of starting materials and powder blends. This presentation focuses on the novel techniques used in pre-formulation studies which assist the design and optimization of formulation and processing conditions. Total quality control demands high standards from every aspect of production, from the starting materials to processes and equipment, right down to the final product handling and storage. In addition, tools to monitor a production process will be useful and some of these will be discussed.

Principles of Multiple Dosing Pharmacokinetics

Sunil S. Jambhekar
Associate Professor of Pharmaceutics, Dept. of Pharmaceutical Sciences, Massachusetts College of Pharmacy/HS
179 Longwood Avenue, Boston, MA 02115

Abstract of the Plenary Lecture:

Pharmaceutical scientists serve patients and health care providers by possessing and applying comprehensive knowledge of physico-chemical principles in developing effective drug delivery systems and pharmacokinetics principles in establishing optimum dosage regimen for a drug therapy in clinical situations. Therefore, a pharmaceutical scientist must fully understand how a development of drug delivery systems, variation in pharmacokinetics of drugs, and varying disease states influence a patient's response to the administered dose of a drug.

Some drugs, for example, analgesics, neuromuscular blocking agents, bronchodialators, and antiemetics, may be used effectively as a single dose. Most drug therapy, however, involves repeated administration of separate dose of drugs over a variable time period and, hence, are administered on a continuous basis. In this aspect of a drug therapy, multiple dose kinetics plays a particular important role.

When drugs are administered on a continuous basis with sufficient frequency, measurable and more frequently pharmacologically significant level of the administered dose of a drug remains in the body prior to the administration of the subsequent dose. Therefore, factors that are important to know are how long the drug therapy should be continued, whether a few days for muscle pain and antibiotics or prolonged period for an anti-hypertensive or anti-diabetic or anti-anxiety agent to achieve the optimum blood level profile; what type of drug accumulation, if any, will occur with repeated administration of drug doses; and how long will it take to attain steady state level of the desired blood level. Therefore, for any drug intended for long term use, it is important to examine the pharmacokinetics under multiple dosing conditions. Additionally, multiple dose studies may provide important information not obtainable in a single dose studies; for example, peak and 'trough' characteristics.

Administration of drugs by multiple dosing enables one to attain the desired plasma concentrations rapidly and then maintain it within desired levels by adjusting the dose and the dosing interval of the drug administered. The fluctuation and accumulation, indelible features of multiple dosing, can be controlled by selecting proper dosing interval for each drug. This approach, therefore, enables one to achieve blood levels within the therapeutic and/or effective range continuously over a prolonged period. For drug administered at a constant dosing interval and in a fixed dose, the peak and 'trough' plasma levels following the administration of second and succeeding dose of a drug is always higher than the peak and 'trough' levels for the first dose as a consequence of drug accumulation in the body relative to the first dose.

This presentation is based on a simple one compartment model and first order kinetics. Another important assumption is that identical dose of a drug is administered at an identical dosing interval, which may not always be applied in practice. The more irregular the dosing interval, the greater is the difficulty in characterizing and predicting drug accumulation and actual steady state plasma concentrations.

Regulatory issues with respect to NDA and ANDA

S.W. Deshpande
Secretary General, AIDCOC, Mumbai

Changes to an approved Drug Master file (DMF) for active pharmaceutical ingredients (APIs), Abbreviated New Drug Application (ANDA) of a dosage form in the United States (US) and Marketing authorization applications (MAA) of a dosage form in the European Union (EU) constitute a very major & important part of regulatory affairs function in pharmaceutical organizations dealing in regulated markets like US & EU.

The urgencies & speed needed at the time of filing (such as from a pilot plant) and changes needed by manufacturing & quality control at the time of commercialization of the product trigger the need for notifying/ filing changes to regulatory agencies as an Annual update (in US), Changes being effected (CBEs in US)/ Type I variations (in EU) or Prior approval supplement (PAS in US)/ Type II variations (in EU).

Although in an ideal scenario, commercial manufacturing should immediately follow an approval, in many instances it becomes paramount to apply for changes in the filings to ensure compliance to all the regulatory commitments and facilitate commercial & manufacturing needs of the product. This may be as a result of commitments made during the approval process e.g. Mutual Recognition Procedure (MRP) in the EU (e.g. changes to tablet shape needed by a particular EU country) or assisting manufacturing need (e.g. change in batch size of the product).

Guidelines provided by US FDA e.g. BACPAC (Bulk Actives Post Approval Changes), SUPAC (Scale-up Post Approval changes) & Changes to approved NDA & ANDAs, and European Commission notice to applicant (Guideline on dossier requirements for Type IA and Type IB notifications) will be discussed.

The presentation aims at bringing a harmony in the understanding on managing post approval changes in regulated markets of US versus EU, and notifying the regulatory agencies accordingly, in order to comply to the regulatory requirements for these markets. The documentation requirements for various categories of post approval change filings will be discussed.

Drug treatment of Alzheimer's disease: Global and individual perspectives

Stefan Kowalski
Senior Clinical Pharmacists, Co-ordinator Pharmacy Information System, Department of Pharmacy Al Khod, Muscat, Oamn

Stefan Kowalski, Senior Lecturer in Clinical Pharmacy, School of Pharmaceutical, Molecular and Biomedical Sciences, University of South Australia, Adelaide, SA 5001

Alzheimer's Disease (AD) is a progressive degenerative disease initially identified by German physician Alois Alzheimer in 1907. It is the most common cause of dementia with patients presenting with memory impairment and a variety of other symptoms. Alzheimer's disease is not part of the normal ageing process and transgresses all social, economic, ethnic and geographical boundaries. The 10/66 Dementia Research Group has noted that: less than one tenth of all population-based research into dementia has been directed towards the two-thirds or more of all people with dementia who live in developing parts of the world[1].

Although a common condition, each affected individual will present in their own unique way. As the disease progresses the neuropsychiatric problems that occur will present specific challenges for relatives and carers.

At present there is no cure for the disease : The goals of treatment for patients with Alzheimer's disease are to improve or at least reduce the loss of memory and cognition and to help maintain independent function. Drug treatments for Alzheimer's disease can be broadly divided

into cholinesterase inhibitors, drugs for managing psychiatric and behavioural symptoms, agents designed to slow progression of the disease and agents to modify the degenerative disease process.

Cholinesterase inhibitors decrease breakdown of acetylcholine and thereby reduce the apparent deficiency of cholinergic neurotransmitter activity that is seen in Alzheimer's disease. Cholinesterase inhibitors do not halt or reverse the progression of the disease but may improve symptoms or stabilise decline. They are indicated for the treatment of mild-to-moderate Alzheimer's disease and a clinically relevant improvement in cognition, equivalent to about 6 months of preserved cognitive function, is seen in about 10% of patients.

Depression, delusions, hallucinations, agitation, anxiety, apathy, irritability and wandering are all frequent accompaniments of Alzheimer's disease. Non pharmacological therapy is preferred for many of these neuropsychiatric manifestations with drug therapy being reserved for depression, suppression of psychotic symptoms, aggression and agitation. Since most patients with Alzheimer's disease are elderly, it is important to consider the pharmacology and side effect profile of a drug in order to produce the optimum balance between response and side effects.

Several therapeutic agents have been investigated in an attempt to slow the progression of Alzheimer's disease. Although results have generally been poor, investigation in this area is ongoing. Of particular interest is memantine, a non-competitive NMDA receptor antagonist, has recently been demonstrated to slow the rate of deterioration in patients with moderate to severe Alzheimer's disease

Therapeutic Drug Monitoring Vs Target Concentration Intervention: Which is the right strategy in indvidualization of drug therapy?

Devarakonda R. Krishna
Professor, University College of Pharmaceutical Sciences
Kakatiya University, Warangal – 506009

Therapeutic drug monitoring (TDM) refers to the individualization of dosage by maintaining plasma or blood drug concentrations within a target range (therapeutic range, therapeutic window). There are two major sources of variability between individual patients in drug response. These are variation in the relationship between:

A. Dose and plasma concentration (pharmacokinetic variability)

B. Drug concentration at the receptor and the response (pharmacodynamic variability)

By adjusting doses to maintain plasma drug concentrations within a target range, variability in the pharmacokinetic phase of drug action is greatly reduced.

The characteristics of drugs which make them suitable for, or make them require, therapeutic drug monitoring are:

1. Marked pharmacokinetic variability
2. Concentration related therapeutic and adverse effects
3. Narrow therapeutic index
4. Defined therapeutic (target) concentration range
5. Desired therapeutic effect difficult to monitor

It is however, time to pay attention to the concentration – effect relationship and to think about right strategy of individualizing drug treatment with the aid of drug concentration measurements.Target concentration intervention (TCI) – is a new treatment 'strategy' unlike TDM. It has been proposed that TCI as an algorithm for rational dose individualization, whose essential feature is to use a target concentration rather than a 'range'. This strategy does not aim to have the measured concentration equal to the target concentration. This is the key distinction from TDM, which aims to have the measured concentration within the therapeutic range. TCI approach explicitly uses a PK model to understand what makes the patient an indvidual while TDM offers no direct guidance and leaves the physician to use any method to get the concentration within the 'range'.

The therapeutic range concept suffers from two deficiencies, one is related to validity of prscribing the desired dose and the other is related to the implicit assumption that all concentrations within the 'range' are equally desirable.

The TCI strategy requires the selection of a target effect first and then the target concentration to achieve that effect. The target effect may vary with time as the disease state changes.

Top Floor to Shop Floor: In Pharmaceutical Industry

Dnyanesh Arun Limaye
Head, Drug Regulatory Affairs, Aventis Pharma Ltd
54/A, Sir Mathuradas Vasangi Rd., Mumbai 93.

Pharmaceutical and biopharmaceutical enterprises continue to face complex regulations and increased scrutiny from regulatory agencies related to the safety and efficacy of their products—from discovery and license approval through ongoing supply to the consuming public. These complexities and increased scrutiny can result in large fines and production shutdowns, making "top floor" executives more concerned with day-to-day "shop floor" operations. Although the initial push to focus on production control activities follows on the heels of unsettling events, many pharmaceutical and biopharmaceutical manufacturing executives are discovering that information systems are the key to providing reduced costs and increased competitiveness in the face of increasing regulatory pressure.

The lack of ability to communicate information/data between executives, operations personnel, facilities and regulatory agencies, however, is a source of growing concern as top managers become more involved in daily operational activities. Managers and production personnel have historically worked in silos. Even when senior managers focus on operations, they are concerned with financial management, job management, production management and materials management. Production personnel, on the other hand, typically zero in on specific processes and product order fulfillment activities.

Additionally, the FDA and other regulatory agencies must oversee compliance to rules, practices and legislation governing drug production. Until recently, these agencies had to wade through mountains of paper to ensure a firm's compliance.

Now, they use electronic documents, data and records to carry out their enforcement and compliance mission. So a successful information system must also bridge the information collection, reporting and management challenges that manufacturers and regulatory agencies face in trying to cooperate and communicate with one another.

Developing a technology infrastructure that promotes the sharing of information from top floor to shop floor takes considerable effort, but the benefits can stretch far beyond simply increasing compliance and quality. The sharing of information can help pharmaceutical and biopharmaceutical manufacturers compete more successfully and operate more profitably. Reduced manufacturing costs, combined with increased capacity, utilization and efficiency, equals less pressure on earnings. In fact, running a highly automated and cost-efficient production facility could become the key to success, especially as new drug launches become less common and competition becomes more intense.

Medicines Management - An Insurance Policy for Safe Practice

Malcolm B R Partridge
Chief Pharmacist, Queen's Medical Centre
Nottingham, NHS Trust, NG 7 2UH

Medicines Management encompasses the whole process of medicines usage. From the very outset deciding on which drugs should be used, their purchase, storage, prescribing, dispensing, in-use storage, and administration to the patient - are all important and critical processes. Beyond that, drug surveillance in clinical use enables adverse events either as side effects or as medication errors to be captured and lessons learnt and actions taken.

At each of these stages decisions are taken and risks can occur. If these are ignored, not fully appraised, or safe systems not put in place there is the potential for ineffective drugs for example, because they have not been stored properly or very real harm to patients for example, because a nurse did not have the knowledge or skills to prepare an intravenous drug correctly.

Throughout all these various stages of medicines management pharmacists must play an essential and key influencing role.

Only drugs that have a proven evidence-based effectiveness and safety profile should be brought into clinical practice. Pharmacists can bring expertise and influence into these decisions through active participation in hospital Drugs and Therapeutics Committees. Tough decisions must be taken when the proposed new drug has only marginal benefit and perhaps does not address the prevailing healthcare priorities.

Once it has been agreed to bring a new drug into routine clinical use pharmacists must determine safe systems for the use of the drug in practice through engaging a multidisciplinary Medicines Management Team. In such a forum issues such as prescribing policies, storage, training and systems for safe drug administration and operational standards are determined.

When things go wrong and medication errors occur, pharmacists should take a leading role in assessing what went wrong and why and advise on the actions required to reduce future risk. This can be undertaken in an open and challenging culture through a "no-blame" reporting policy and evaluation by a Drug Related Incident Group.

To not participate in theses several aspects of medicines management could be considered a professional abdication of duty. Pharmacists must accept accountability for these roles if they are to exert influence and seek professional credibility.

For governments or organisations, not to invest in pharmacists' input into medicines management at all levels diminishes the potential for achieving best and safest practice for our patients.

This presentation will describe how one large Teaching University Hospital, Queen's Medical Centre, Nottingham, England, has invested in pharmacists' time into these various facets of medicines management as an "insurance" policy that helps assure safe and effective practice.

Application of Particle Technology in Pharmaceutical Industry

B.Pitchumani
Particle Science and technology Laboratory
Chemical Engineering Department
Indian Institute of Technology, Delhi
Hauz Khas, New Delhi-110016

Powders are used in drug manufacture either as raw material or intermediate or as final product. The behaviour of powder and characterisation of powder is given minimum importance and mostly it is carried out on iterative procedure. The subject has been studied as particle technology and recently it is studied as particle design. The process of drug manufacture involves unit operation such as crystallisation, filtration /centrifugation drying, aggolomeration and pulverization.

The most important of these is particle characterisation which involve in measurement of size, size distribution, shape, bulk density, zeta potential etc.

In Pharmaceutical industry the potency of the drug is the controlling factor. It increases with decrease in the size of the basic particle. It also depends upon shape of the particles. The particles with higher asperities will have higher potency. Hence morphology is also one of the important property of the for the drug production. It has become to notice many times good particles are produced during crystallization and final product after it goes through other unit operation like fluidised bed drying the particles loose many of the desired qualities. Similarly selection of dryers should be taken into basic particle nature and final shape to be obtained. The shape is not quantitatively defined during drug manufacture either due to the ignorance or want of instrument and interpretation of the measurement.

In one of the case study it was observed the drug is less pure but potency is high. It as rectified when process was improved by studying the effect of process variables on the shape of powder product.

It has been seen in one case the filter element was getting damaged frequently due to wide size distribution present in the slurry.

It was observed in one case study that the pulverized material had very wide size distribution with larger proportion of fines. The purlverizer should be studied on the basis of comminution functions such as selection function and breakage function. This will help to control particle size distribution to desired level condition.

The paper will discuss the importance of size, size distribution, shape and zeta potential on the various unit operations such as filtration, drying and pulverisation.

Role of Biological Assays in the Standardization of Herbal Drugs

M. K. Raina
Consultant – Ayurvedic & Herbal Medicines
3088, Oberoi Garden Estate, C – Wing
Chandivali Road, Saki Naka, Mumbai - 400072

The importance of standardization of herbal drugs is now well understood by the consumer as well as the industry. Standardization helps in effective quality control during commercial production of such drugs since Pharmacopoeial standards are not adequate in most cases. In the past, the Ayurvedic physician would himself prepare small quantities of medicines for his patients but due to commercialization, the need for standardization has become important and necessary.

During last two decades or so, emphasis has been laid on chemical methods of standardization based on physical, chemical assays, chromatographic analysis and various spectroscopic methods. Most of these are qualitative methods though many plant materials have been standardized quantitatively using HPLC and HPTLC and these methods are used as an effective quality control parameter. In such cases, chemical markers have been isolated and characterized. In several plant materials spectroscopic methods of standardization have also been found to be useful. However, marker compound based standardization in many cases has not been as effective since these markers are not biologically active constituents in most of the cases.

All these methods account for a single chemical entity or a group of chemical compounds, but in many plants the activity may be attributed to different types of compounds that act synergistically to show the desired biological activity. Therefore, standardization by chemical methods, although used widely, may not prove to be a complete way of standardization.

Biological Assays

The use of bioassays has been found to be an effective method in standardization and quality control of herbal materials. Though this method of standardization is not yet popular as compared to chemical methods, the trend all over the world is now on use of biological assay methods in addition to chemical methods, which ensures consistent clinical efficacy of the herbal product from batch to batch. It has also been observed that analytical methods including chromatographic evaluation sometimes are ineffective as they are usually insensitive to the chemical complexities found in crude botanical extracts. It is well established that the biological potency of the herbal drug is due to not one but a mixture of bioactive plant constituents and the relative properties of single bioactive compound can vary from batch to batch while as the biological activity remains within the desirable limits. Therefore, it is desirable to incorporate bioassays as an additional method of standardization, which in turn becomes an effective quality control method.

Bioassays are broadly classified as

a) General screening bioassay
b) Specific bioassays and
c) Primary screening bioassays

The General screening bioassays are non-selective and indicate the biological activity of the herbal drug. The drugs showing positive activity are further taken up for specialized assays for their specific activity. Any active compound isolated from the plant becomes a biomarker. The general bioassays include Hippocratic screening where in intact animals are used and involve the effect of the plant extract on gross behaviour of the animals. The isolated organ method using guinea-pig ileum is more common since it is relatively simpler to undertake. The Brine Shrimp Lethality Test involves lethality to brine shrimp nauplii. Its main use is for detecting cyto-toxicity. The Specific bioassays provide specific bioactivity and a large number of herbal drugs have been standardized using this method, example being anti-inflammatory, anti-oxidant drugs, etc. The Primary screening bioassays are relatively simple and also help in identification of bioactive compounds.

The use of bioassays is promoted and encouraged since these are relatively inexpensive, rapid and technologically simple requiring little training. Some of the common ones are:

a) Brine Shrimp Lethality – It is a rapid general bioassay for bioactive compounds. The in vivo lethality in a simple zoologic organism can be conveniently used to monitor screening and fractionation in the discovery and monitoring of bioactive natural products. The eggs of brine shrimp, Artemia salina (Leach) are readily available at low cost and remain viable for years in dry state. Once placed in seawater, the eggs hatch within 48 hours to provide large number of larvae (nauplii) for experimental use.

b) *Brown Gall Tumours on potato discs - This is an animal-sparing bioassay for anti-tumour compounds. Crown gall is a neoplastic disease of plants induced by specific strains of the Gram-negative bacterium, Agrobacterium tumefaciens. It has been seen that the inhibition of crown gall tumours on discs of potato tubers showed an apparent correlation with compounds and plant extracts known to be active in murine leukemia anti-tumour assay.*

c) *Frond Inhibition of Lemna – This is a specific bioassay for plant growth stimulants and inhibitors. Lemna minor is a miniature aquatic monocot and consists of central oval frond or mother frond with two attached daughter fronds and a filamentous root. Under normal conditions the fronds produce exponentially with buddings of daughter fronds.*

d) *Yellow Fever Mosquito test – It is a specific bioassay for pesticides and can be used to determine the pesticidal activities of botanical extracts, their fractions and isolated compounds.*

Bioassays thus can play an important role in the standardization of herbal drugs, and can also become an important quality control method as well as for proper stability testing of the product.

Bioassays thus appear to support argument that marker compound levels may have some relation to biological activity in some plant materials. Therefore, bioassays seem to offer a new direction for analysis of herbal drugs leading to effective quality control.

Neuromuscular Blockers as Potential Pharmacokinetic/Pharmacodynamic Probe of Graft Function during Liver Transplantation

Iqbal Ramzan
Associate Professor, (Pharmaceutics & Anaesthesia)
Associate Dean, (Admissions & Administration)
Faculty of Pharmacy, The University of Sydney
NSW 2006, Australia

Liver transplantation is an effective treatment for end-stage liver disease. However, post-operative complications may lead to patient death unless urgent re-transplantation is performed. It is therefore critical to detect graft functional status early during liver transplantation. While numerous liver function tests are available, these primarily reflect hepatobiliary damage rather than activity of the functioning liver cells. Liver function may also be assessed by clearance of certain indicators or drugs like indocyanine green or lignocaine. These, however, do not satisfy the critical requirement of early detection of dysfunction after graft reperfusion. Measurement of paralysis induced by neuromuscular blockers metabolised by the liver has also been used for early assessment of graft function. A significant correlation between recovery from vecuronium or rocuronium and graft function during the early post-operative period has been observed with prolongation of recovery in patients with graft dysfunction.

Following assay development for plasma rocuronium in liver transplant patients and using a reliable neuromuscular function monitoring system (TOF-GUARD®), two studies examined rocuronium's utility as a potential pharmacokinetic and/or pharmacodynamic probe of graft function. In the first study, rocuronium plasma concentrations during different phases of the operation were compared when it was infused at a constant rate throughout the operation. Compared with the an-hepatic phase, a decrease in rocuronium plasma concentration was observed during the neo-hepatic phase in all (14 of 17) patients who had normal graft function post-operatively. In contrast, increases in rocuronium plasma concentrations during the neo-hepatic phase were observed in three patients, of these two had abnormal post-operative liver function tests and died within one week post-operatively. In the second study, rocuronium infusion requirements during different phases of transplantation were examined when constant paralysis was maintained during the operation. Rocuronium requirement during the an-hepatic phase was significantly lower than during the paleo-hepatic phase, suggesting decreased rocuronium excretion during this phase. In most (14 of the 16) surviving patients, rocuronium requirements during the neo-hepatic phase were either increased or remained unchanged compared to the an-hepatic phase. Rocuronium requirement during the neo-hepatic phase was decreased in the only patient who had high liver enzymes post-operatively and who died post-operatively. Collectively these results confirm rocuronium's utility as a real-time pharmacokinetic and/or pharmacodynamic probe of graft function during liver transplantation provided rocuronium is assayed and neuromuscular function is quantified.

Export Potential of NDDS - A Growth Perspective for Indian Pharma Industry

Sachin C. Itkar
Managing Director, Bill Care Pharma Packaging Research
Plot No. 365, Sector 24, BH Sant Tukaram Sankul
Nigdi Pradhikaran, Pune 44

With the onset of the product patent regime in 2005, Indian Pharmaceutical Industries are looking at new equations for competitiveness with research & development emerging a crucial factor. Indian Pharmaceutical Industries have also been successful in tapping the NDDS opportunities for enhancing the global Pharma market share.

Today, novel drug delivery system (NDDS) is a buzzword among the local Indian Pharma Industries. Whether large or medium, many Indian companies are at some stage of NDDS. It offers immense opportunities to Indian companies as many new drugs which were introduced in 1980's will be seeing the patent expiries in the coming 3 / 4 years. Since more than 30 blockbuster drugs will lose patent protection, there will be a significant gap in the portfolio of the companies marketing them. NDDS could be a strategic tool for expanding the markets & extending the product life cycle.

The global market for the NDDS drugs is estimated at $ 20 – 22 billion & is expected to double in coming 5-6 years. It offers immense opportunities for the Indian Pharma industries especially in the research & development of NDDS.

The Indian Pharma companies are rushing towards NDDS as the development time is less and the cost of the development is much lower as compared to a new chemical entity. NDDS means an economical & accelerated means to market. In general the average cost for a new NDDS is $ 15 million to $ 50 million with a development period of 5 to 7 years. This represents a small fraction of R & D expenses for a new drug discovery & research program which costs around $ 300 million to $ 600 million & a development period of 10 to 12 years.

Today, about 74% of drugs are taken orally and are found not to be as effective as desired. Thus, various forms of NDDS such as transdermal delivery systems, controlled release systems; transmucosal delivery systems, intranasal delivery, liposomal delivery, pulmonary delivery, taste masking, needle free delivery etc. emerged.

Export Potential

The health scenario demands the development of NDDS for more than 20 diseases & conditions for the developing & underdeveloped countries. It is a great challenge & opportunity for the

Indian Pharma Industry to explore & exploit these markets as the export of NDDS to these countries is concerned.

The facilities created during the development of NDDS can also lead to export of technologies as well as attract foreign collaborations as India has proven strengths in process technologies & cost effective manufacturing.

The talk will provide a thorough understanding of various types of NDDS used worldwide, India's strengths & competitiveness in manufacturing & exporting NDDS to the rest of the world, the potential export markets for NDDS formulations & technologies with the detail market analysis & the export strategies to be adopted to be successful in these markets.

Nuclear Medicine Imaging - a development tool in Pharmaceutical Research

Rakesh Kumar Sharma
Joint Director, Institute of Nuclear Medicine and Allied Sciences (INMAS), Brig. SK Mazumdar Road, Delhi

Nuclear Medicine (NM) techniques are used to provide dynamic, non-invasive and real-time information on the in vivo behaviors of radiolabeled molecules. Radiopharmaceuticals are compounds linked to radionuclides that are tailored for preferential localization in an anatomical lesion, a particular organ or physiologic/ pathologic process. NM technology has the potential to affect the drug development process during a very early stage, when a drug is undergoing animal testing. The development of dedicated high resolution small animal scanners has made it possible to assess the time course of uptake of a drug in experimental animals. NM has also been successfully used in evaluation of the pharmaceutical dosage forms.

Pharmaceuticals labeled with single-photon emitting radionuclides are exploited to provide high-resolution images on Planar Gamma Camera or Single-Photon Emission Computed Tomography (SPECT) scanner. NM techniques can impart knowledge about the time course of uptake, the spatial distribution, and the functional effects of a drug. The introduction of cyclotron-produced short-lived positron-emitting isotopes of the basic elements of life such as carbon, nitrogen & oxygen etc., and Positron Emission Tomography (PET), has added interesting dimensions to the applications that include assessment of blood flow and metabolism, receptor imaging, elucidating the pathophysiologic process, evaluating role of labeled therapeutic agents, and the potential of these techniques in the development of novel therapies & monitoring their therapeutic response. It is also possible to characterize cell membrane and macromolecular receptor recognition sites such as receptors, enzymes and neurotransmitters using appropriate radiopharmaceuticals. It is possible to image molecular interactions of biological processes in living systems using NM techniques. The anatomical distribution and localization of radiolabeled drugs obtained can be used to generate real time receptor occupancy and off-rate studies. Functional imaging methodology plays a major role in understanding the basic mechanisms of a multitude of disorders, accurate diagnosis of certain diseases, multidrug resistance phenomenon and developing effective treatment for serious illnesses such as cancer and central nervous system maladies. As the radiolabeled drug are administered in subpharmacological doses, preliminary studies on their pharmacokinetics and the assessment of their effects on metabolism can be safely carried out even before the drug has entered in Phase I trials. Such studies can provide cost-effective predictive toxicology data and information on the metabolism and mode of action of drugs.

NM can also help bridge the gap between molecular biology, understanding of pathology and to the design of a new generation of drugs. NM Imaging could thus, become a major locus in drug development efforts in the next decade as we enter a new age of certainty where diseases will be viewed as molecular dissonance or a communication disorder and more specific radiopharmaceuticals and the scanners with higher sensitivity will be easily available.

Rational Approaches to Drug Discovery

S.P. Gupta
Professor of Chemistry
Birla Institute of Technology and Science (BITS)
Pilani (Raj.) - 333031

The rationalization of drug discovery drastically reduces the cost and time of investigating a potential drug against any disease. It addresses the following important questions: (1) what features or physicochemical properties of a molecule affect its activity, (2) what can be modified to enhance its activity, (3) what is its mode of action, and (4) can we predict the activity of any drug molecule before its synthesis. All these questions are very well answered by QSAR (quantitative structure-activity relationship) and molecular modeling studies. We propose here to discuss some of the very popular methodologies for such studies.

Special Delivery Strategies In Helicobactor Pylori Treatment

N.K. Jain
Professor, Department of Pharmaceutical Sciences
Dr. HS Gour Viswavidyalay, Sagar (M.P.)

The paradigm of no acid-no ulcer was challenged 16 years ago by a gastroenterologist, Dr. Barry Marshall and a pathologist, Dr. Warren from Australia by suggesting that Helicobacter pylori (H. pylori) caused duodenal ulcer. The International Agency for Research in Cancer (IARC) declared H. pylori to be a Group I carcinogen, a definite cause of human gastric cancers. Recently, World Health Organization (WHO) revised the pathophysiological approaches by identifying the bacterium H. pylori as the causative organism for peptic ulcers. The virulence factors are of two types: the colonization factors and the tissue invasive factors.

Treatment of H. pylori infection is difficult for three main reasons:

- *Once acquired, H. pylori penetrate the gastric mucus layer and the organism exclusively resides on the luminal surface of the gastric mucus under the mucus gel layer and access of antimicrobial drugs to the site is restricted, both from the lumen of the stomach and from the gastric blood supply.*

- *H. pylori may have acquired resistance to the commonly used antimicrobial agents.*
- *Degradation of antimicrobial agents in acidic environment.*

Most antibacterial agents have low minimum inhibitory concentrations (MIC) against H. pylori in culture. However, single antibiotic therapy is not effective for the eradication of H. pylori infection in vivo. The antibiotics are not delivered to site of infection in effective concentrations and in fully active form from the conventional drug delivery systems.

It is necessary to design drug delivery systems, which could not only curtail and alleviate the shortcomings of conventional delivery vehicle, but also place the antimicrobial to the infected cell lines. It is expected that if local delivery of antimicrobial agents from the gastric lumen into the mucus layer can be achieved then H pylori eradication rate will be increased. Secondly, the drug must diffuse into the mucus layer and the bacterial glycocalyx to furnish concentrations sufficient for antibacterial activity. Lastly, the contact time of antibacterial agents with the organism needs to be sufficiently long. Therefore, better stability and longer residence time will allow more of the antibiotic to penetrate through the gastric mucus layer to act on H. pylori. It can be expected that topical delivery of narrow spectrum antibiotics through a gastroretentive drug delivery system or site-specific drug delivery system may result in complete removal of the organisms in the fundal area of the gastric mucosa due to bactericidal drug levels being reached in this area, and might lead to better treatment of peptic ulcer disease.

Various therapeutic approaches in gastroretentive and site-specific drug delivery systems have been developed and investigated. Multiple unit floating drug delivery systems like floating microspheres, floating-bioadhesive microspheres and ion-exchange resin based floating drug delivery systems were developed and the efficacy of formulations investigated. Other than gastroretentive drug delivery systems, receptor mediated (site-specific) drug delivery systems; like ligand mediated gastroretentive system has also been tried for the treatment of H. pylori. The rationale for site-specific targeted delivery may be appreciated as a set of desirable events including an exclusive delivery to specific compartments with maximal potential intrinsic activity of drugs and concomitantly reduced access of drug to irrelevant non-target cells. The targeted delivery to previously inaccessible domains such as H. pylori offers distinctive therapeutic potential in the H. pylori treatment.

Realization that many gastroduodenal diseases, such as peptic ulceration are indeed infectious diseases, has caused a complete reconsideration of their management. The possibility of the production of an anti-H. pylori vaccine and the likelihood that it will have a therapeutic effect could be the next revolution in the management of these diseases.

Self Care – a program to provide both professional and financial reward for community pharmacy

John Alfred Bell
President, Commonwealth Pharmaceutical Association
4, Carnarvon Road, Reseville, NSW 2069, Australia

Pharmacy Self Care is a consumer health information program developed by the Pharmaceutical Society of Australia to enhance the role of the community pharmacist.

The program, which was established in 1986, provides up-to-date, objective and authoritative health information to consumers and a comprehensive training program for pharmacists and their staff. It is supported by a regular promotional program through print and electronic media.

From an original base of around 400 pharmacies in the state of New South Wales, now over 40% of all Australian pharmacies nationally subscribe to the program. Pharmacies in Fiji and Zimbabwe also subscribe to the Australian-based program and the Pharmaceutical Society of New Zealand has adapted the program for us in that country.

Pharmacy Self Care (PSC) is supported by industry, government and consumer organizations. It addresses the need for consumer information on health conditions and issues in a way that builds respect and loyalty for community pharmacy.

The PSC model has been developed by the Commonwealth Pharmaceutical Association to carry out malaria awareness campaigns in sub-Saharan Africa. The Pharmaceutical Societies of Ghana and Tanzania are currently undertaking evaluation of recent programs on this disease. Pharmaceutical Societies in Kenya and Guyana

have also expressed interest in using the PSC template to promote the pharmacist and improve health outcomes.

Pharmacy Self Care can certainly provide the platform for long term professional and retail success.

This presentation will propose ways that PSC can be used in India to promote community pharmacy.

Changing Needs In Pharma Curriculum In India

M. S. Nagarsenker
HOD & Professor of Pharmaceutics
Bombay College of Pharmacy, Kalina
Santacruz (E), Mumbai 400098

Pharmacy education is responsible for preparing students to function as professionals and inform citizens in changing health care systems. It is also responsible for generating and disseminating knowledge about drugs and pharmacy care systems. Pharmaceutical education pattern was designed in 1960's and 70's based on prevailing needs of pharmaceutical field. In curriculum more emphasis was given to industrial pharmacy as it was fast developing field. Attention was also given to information and research in natural products and phytochemistry as these fields showed great promise because of diverse and rich fauna and flora of India. Less attention was paid to hospital pharmacy, clinical pharmacy / community pharmacy.

Pharmaceutical field in India in last four decades has undergone major changes. It is the second fastest growing industry in India next to information technology. Significant changes in health care systems have taken place in recent years. Pharmacist's role has become more specialized and more demanding. It has necessitated identification of more subjects and areas in which pharmacist should undergo training.

The presentation will briefly describe present status of Pharma field in India and changes that have taken place over a period of time. Based on this assessment presentation will identify the areas of training and change in approach in designing basic curriculum.

Pharmacy Education: A Vision for the Future

The International Pharmaceutical Students' Federation (IPSF), founded in London in 1949, now represents 325,000 students and young pharmacists from 74 countries. It is a non-profit, non-political and non-religious organization whose aim is to promote the interests of pharmaceutical students and to encourage international co-operation among them.

The educational opportunities for students and young pharmacists differ greatly in countries represented by IPSF. Often education of pharmacy students is limited by access to educational resources and non-exposure to innovative teaching methods. IPSF is working to drive policy change by creating opportunities for improvement in pharmacy education.

At the recent IPSF-EPSA Joint Symposium on Pharmacy Education, conducted in Strasbourg during October, presenters from all over the world gathered to discuss new and innovative ways that pharmacy education can be improved.

Mobility in pharmacy education is an important factor in preparing pharmacy students to work in a rapidly changing global environment. Mobility of both academics and students has become an important aspect of tertiary education. Last year the IPSF Student Exchange Program placed more than 420 students and young pharmacists on international exchanges in over 45 countries.

The Asia Pacific Regional Office of IPSF recently collaborated with the Western Pacific Pharmaceutical Forum of FIP to produce a statement of principle entitled The Pharmacist and Public Health. An extremely important part of this statement related to topics that pharmacy schools should include in their curricula in order to equip future pharmacists to provide public health services.

The IPSF roadmap for pharmacy education is outlined in the document: "Pharmacy Education: a Vision for the Future".

Pharmacists in Rajasthan

P.C. Dandiya
Emeritus Professor of Pharmacology
S.M.S. Medical College, Jaipur

The WHO's active interest in Rational Use of Drugs is now 26 year old and in these years it has interacted with more than 150 countries' governments, the health personnel including administrators, physicians, nurses, pharmacists and even the consumers. In the last few years the interaction with the pharmacists has been increasing. In Switzerland (1977) a project jointly worked out by the physicians and the pharmacists yielded encouraging results in human, professional and economic terms. In India (W.Bengal) a training course (1999) conducted for hospital pharmacists was highly successful. For some years the WHO, the European Union Commission, and the MSH group of Washington have been active in Rajasthan and in 2002 representatives of DSPRUD, RSPRUD, WHO Essential Drugs Programme, the DPT and the AIO of Chemists and Druggists jointly brought out a document now known as the "Jaipur Declaration" which when implemented could enhance the availability of medicines for the 70 % of India's population that is deprived of them presently. As a sequel to this the WHO through the DSPRUD has enabled us make a survey of the of the present status of Pharmacist in Rajasthan.

Two hundred community Pharmacies, were surveyed without prior notice in two districts ie Jaipur and Ajmer of Rajasthan At 67.5 % of the establishments the license holder pharmacist was found on the job and the rest were functioning without the license holder during the period of the survey. In these 200 establishments the license was in the name of a diploma holders (52.5%), degree holders (1.5%) and those who had it on experience basis (45%). The ownership break up of these 200 was proprietor-pharmacist 42.5%, employee pharmacists 41% and the rest were non-professionals. Of these 200, 71.9 % remained open for 7days/week and 21.8% for 6 days; 37.2 % opened it for 85 hours a week and the others varied. While 40.7% claimed to dispense /sell 301 to1200 hundred prescription /items per week, 59.3 did less than 300. In 28.1% the average cost of the prescription was between Rs 101 to 200, in 46.7% it was between Rs 50 –100 and in 3.5% it was more than 200. Of the respondents65.8% felt that at least 1 client /week was suspected to be misusing a drug while 8% claimed it could be 6-10/week. A percentage of 48.7 claimed to be making a personal/telephonic contact with the physician 2-5 times a week while 34.2 did it once a week. Most Pharmacists felt that there was no shortage of pharmacists or lack of adequate knowledge. They also felt that absence of extra remuneration was not a barrier in GPP. The survey also provided data on male-female ratio, lack of confidence, views on part-time job, working relationship with, and recognition by the doctors, frequency of refusal to dispense the given prescriptions, illegible writing, similarity in brand names and the role of pharmacist in playing advisor on non-prescription drugs.

Pharmacy in South Africa: An Overview

George K John
School of Pharmacy, Faculty of Health Sciences
Potchefstroom University, Potchefstroom, South Africa.

The objective of this presentation is to provide an overview of profession of pharmacy in South Africa with emphasis on the model of pharmacy education and training. In South Africa in the health sector, 37.7 million people (84% of the countries population) are dependent on the public health care sector for their health care needs. The current practice of pharmacy is undermanned in the public sector with only 1238 pharmacist serving the public sector, while in the private health sector approximately 6500 pharmacist render their services to 7.12 million people. The above inequity in distribuition of services could bring about a serious crisis in the public health sector.

The presentation gives an overview of the general statistics of the pharmacy profession in the country and the key areas of pharmacy operation in the public and private health sector. The presentation focuses on the educational sector of pharmacy to bring about a change in attitude and ways to balance the above mentioned inequity of pharmacist distribuition by starting at the root level of the problem, how to motivate the students to serve the public in especially rural areas.

The unit standards (competency statements) of the regulatory body of the pharmacy profession in South Africa; the South African Pharmacy Council (SAPC) and the other

educational structure regulatory bodies in South Africa which collaborated to form a curriculum based on the Outcome Based Education (OBE) system, which would satisfy the scope of pharmacy practice and the role of a pharmacist in South Africa respectively at the same time maintaining international standards are also overviewed.

Latest Developments on US FDA and EU Guidelines for Pharmaceutical Industry

Ludwig Huber
Compliance Fellow, Agilent Technologies

Although regulations are quite stable, guidance documents and inspection and enforcement trends change much more frequently. Just in the last two months the US FDA released five new guidances related to GMP. Currently there is a major focus towards risk based inspections, initiated by the US FDA GMP initiative for the 21st Century. Driving forces are economic reasons such that both the FDA and the industry will put their resources towards products, processes and equipment that have the highest risk on patient's safety. One of the objectives of this presentation will be to share information on what this new FDA initiative means for imports to the Unites States and how it may influence regulations in other parts of the world and what it means for the pharmaceutical industry. The presentation will be divided into three parts:

1. **Discuss general trends**
   - *Key regulations and new guidelines that impact the pharmaceutical industry*
   - *Enforcement and inspection trends: the trend towards system inspections*
   - *The increasing importance of corrective and preventive action plans (CAPA)*
   - *Major inspection deficiencies for CGMP drug and API inspections*
2. *Impact of US FDA's GMP Initiative for Science and Risk Based Inspections*
   - *History and back-ground*
   - *Objectives of the initiative - focus and science – risk – international harmonization – promote new technology*
   - *Key components of the initiative - risk based system inspections using medical definitive regulations as model, harmonization and predictability of FDA inspection reports – establishment of pharmaceutical inspectorates - FDA cooperation with academia and industry – process analytical technology (PAT)*
   - *Consequences for the pharmaceutical industry*
   - *Impact on validation and compliance of equipment, computers and methods, data and records, e.g, impact on 21 CFR Part 11*
   - *Current progress and next steps*
3. **Initiatives in Europe**
   - *Approach towards compliance in Europe vs. Unites States*
   - *The important role of industry associations, e.g., GAMP and ISPE, and their major initiatives*
   - *The role of ICH and it's new initiatives.*
   - *Situations with e-signatures/records*

The role of the Pharmaceutical Inspection Convention and initiatives, e.g., the new guidance on using computers in GxP environments.

Drug Safety Monitoring - A Global Perspective

Ruth I Ferguson
Specialist Pharmacist, Dunedin Hospital
Great King Street, Dunedin, New Zealand

The association of a case clustering of a rare event (limb deformity in the newborn) and exposure to thalidomide in 1961 identified the importance of drug safety worldwide. In 1963 the World Health Assembly identified the need for the early and rapid dissemination of information on the adverse effects to medicines. In

response, several countries established national monitoring centers. The need to coordinate these national efforts was recognized by the establishment of WHO International Programme for Drug Monitoring and the Uppsala Monitoring Centre (UMC) Sweden, in 1968. The WHO Programme has developed from an initial 9 members to 73 member countries (including India, which joined in 1998) and 9 associate members (of which Pakistan is numbered)[1].

Although there is a thorough evaluation system world wide prior to marketing of a new drug, public exposure rates are low and treatment time short so rare events or those developing from prolonged exposure will not be identified[2]. It is only through mass exposure, exposure of high-risk populations and treatment for an extended time that these risks can be identified. After the marketing of a medicine it is critical that information is gathered on adverse reactions. As governments have the responsibility of legislating to protect the well being of their citizens then the sponsoring of an independent medicines monitoring scheme is an important healthcare responsibility. A national database and over view is important to identify medicines safety issues peculiar to that country. These may relate to the effect of a unique population mix that will influence drug handling and activity, quality of medicines issues, indigenous therapies, access to medicines and disease epidemiology.

At an international level, the pooling of national data into a very large database enables the use of advanced statistical techniques to identify rare or subtle adverse events from the background of disease presentation and diagnostic uncertainty. The dissemination of information on the adverse effects of medicines and education of health professionals is a further important task of an international body[1].

Most member countries of the WHO International Programme operate a spontaneous reporting system. In United Kingdom and New Zealand[3] prescription event monitoring (PEM) systems also operate. Using the New Zealand system as an example, involvement in drug safety monitoring from the governmental level to individual health professionals will be described for both the spontaneous reporting system and for the PEM schemes.

Role of Packaging Materials in the Pharmaceutical & Health Care Industry:

Praful R Naik
President, Bilcare Limited
307, Narayan Peth, PUNE - 411030, INDIA.

N Shenoy
Vice President – Marketing
PRS Permacel Private Limited
63, Bombay Samachar Marg, Fort, Mumbai 400 001

The role of Packaging in Health Care, specifically in Pharmaceuticals has taken an incremental leap in terms of its critical importance as an integral part of the product.

The healthy growth in the global Pharmaceutical sector has also seen a significant importance being assigned to packaging of these products in safe & efficacious packaging systems having additional enhanced features which fulfill the requirements of an active integrate packaging along with the efforts to couple the cost effectiveness factor as well as incorporation of innovative features leading to SMART packaging.

The better understanding of components through specialized research and product services provided by some leading packaging component manufacturers has resulted in a much higher awareness of the Pharmaceutical sector with respect to packaging on a whole and about the critical positive role played by plastics in providing value added packaging components & systems. This is quite evident by the extraordinary growth of plastics in the manufacture of packaging components for Health Care use. The globalization effect is compelling the Pharmaceutical sector in revisiting their existing packaging systems and ways of packaging and converting them into a better, innovative mode of packaging which could be globally acceptable.

The ever increasing pressure of Pharmaceutical sector on the packaging industry to become more novel and overall effective has led to a dramatic change in the R&D thought processes of the packaging industry, propelling it into innovative research by way of utilizing its in-depth understanding of polymers for creating new, innovative products and also orienting its research and development on four key driving forces – Functionality, Time, Price and Global availability.

The Pharmaceutical manufacturing operations are governed in several countries, by a quality code of conduct, which is universally more popularly termed as the Current Good Manufacturing Practices. The cGMP in Pharmaceutical operations are further governed by the Drug regulatory agencies in many of the respective countries, which monitors and enforces stringent guidelines on the Pharmaceutical industries for ensuring the quality, efficacy and safety of the products being manufactured. Although the global industry has understood the critical role of a packaging material, specifically those packaging components, which come in direct contact with the product dosage forms, the same code of conduct applicable to this industry does not get extended to the packaging industry manufacturing these components coming in direct contact with these products. Today, the Pharmaceutical industry world over faces numerous critical challenges, which includes:

- Proper packaging for providing adequate protection to the products for retaining their efficacy and potency through its shelf life.
- Abuse / Accidental misuse
- Counterfeit menace
- Innovative user friendly packaging systems

Key issues with respect to Packaging:

The Pharmaceutical sector has a very strong base in formulation research, resulting in development of highly effective but very sensitive new products for a varied spectrum of conditions, which adversely affect the health of the humans. However, the same level of expertise has not been observed with respect to packaging of these products, specifically in the developing countries, which results in huge losses across the globe due to loss of their critical activity profile over a period of time. This situation is primarily due to not being able to understand the optimum packaging requirement for a specific product. The result is many of the products are grossly inadequately protected against the highly varied environmental conditions across our country and the globe leading to the loss of its functional efficacy in adverse storage conditions over a period of time. Secondly, the sector does not have the right knowledge of the functional uniqueness / limitations of currently available and used packaging constituents as well as their mechanical and chemical properties leading to unscientific and speculative usage. This rather blind way of selection of a specific packaging component results in aberrant observations due to adverse affect of the environmental conditions on the product.

End-To-End Solutions:

There is definitely a need to eliminate this anomaly. Also there is an urgent need to address critical issues like Counterfeit. Bilcare, through its research initiative has been able to come out with a novel solution to address all these limitations.

Bilcare research team has also been successful in using its expertise and understanding of polymers and other materials for developing new innovative packaging components to provide value added viable alternatives for the packaging of the very novel yet very sensitive Pharmaceutical products.

With these critical successes and with several strategic collaborations with companies and institutions of international repute, Bilcare Research program now provides a comprehensive research service package for deliverance of end-to-end innovative, efficacious, viable and cost effective customized packaging solutions for the Pharmaceutical sector. This is completely backed up by availability of packaging materials manufactured in state of the art world-class facility which itself is a benchmark to the global Pharmaceutical & Health care packaging industry, providing Quality products second to none in the world.

Management of Medicines for National Health Care - Presentation

M. Venkateswarlu
Deputy Drugs Controller (India), CDSCO, West Zone, Mumbai

Every Government is committed to the objective of providing health care for its people. The health scenario in the country has undergone significant changes during the past few years. Even today, communicable diseases continue to be the leading cause towards health. Increase in life expectancy and the declining death rate and epidemiological transition is resulting in non-communicable diseases like cardiovascular ailments, cancer, diabetes etc. Some of these diseases are mainly due to change in life styles in the urban population.

The National Healthcare policy was last formulated in the year 1983 and is under revision. The objective of any national health policy is to cater to the needs of the

county's requirements which includes provision of primary and secondary healthcare, providing infrastructure for health care and creating qualified manpower to meet the demands of the health care.

The Governments continuous endeavour is to identify the disease patterns prevalent in the country and draw health programmes to overcome the diseases. The major health programmes that are being addressed by the Government are:

1. National Anti Malaria Programme
2. National Filaria Control Programme
3. Kala Azar Control Programme
4. Japanise Encephalitis Programme
5. Dengue Haemorrhage Fever Programme
6. Leprosy Eradication Programme
7. Tuberculosis Control Programme
8. AIDS Control Programme
9. Blindness Control Programme
10. Iodine Deficiency Control Programme
11. Mental Health Programme
12. Cancer Control Programme
13. Reproductive and ChildCare Programme.

Medicines play a great role in the health care of the people. All the programmes mentioned above require various medicines for prevention as well as treatment. So the medicine management will start with identifying the required medicines for controlling the diseases. After identifying the medicines, it is essential to establish the required quantity for each of the category of the drugs.

It is also imperative that the Government makes a list of essential drugs for catering to the general needs of the public. There is also a need to define a national formulary based on the requirements, which should be a guiding factor for all the practicing Doctors.

The Government has to evaluate as a part of its medicine management system, the pharmaco economics involved in treating each of the diseases. As a part of its evaluation, the Government should consider the options available for them in the range of products available for the management of disease, keeping in view the price at which they are available. As a part of health policy, the Government should also draw a policy for rational use of drugs. An effective policy will help stopping the indiscriminating use of the drugs, particularly antibiotics.

The major components of medicine management can be classified as :

1. Identifying manpower requirements for medicine management.
2. Identification of requirements including infrastructure.
3. Procurement Policy.
4. Evaluation of manufacturers.
5. Procurement of drugs.
6. Distribution and transport of drugs
7. Storage of drugs
8. Post purchase surveillance on quality of drugs.

1. Identifying Manpower Requirements for Medicine Management :

Management of medicines requires manpower who have basic understanding about the manufacture, stock and distribution and the quality parameters involved with these activities. Pharmacists are the key persons who have the basic knowledge and the number of pharmacists require depends upon the volume of drugs to be procured and distributed and the locations where these medicines will be stocked for further distribution either to dispensaries or to the patients. In addition to the pharmacists, people having adequate knowledge in inventory management also be available to have an effective inventory control.

2 Identification of Requirements including Infrastructure:

It is essential to identify the drugs required to be procured for national health programmes, emergencies that may occur due to natural calamities like floods, earthquake and war. The medicines require various different storage conditions. Some medicines like vaccines are required to be stored between 2° to 8° C. Some of the antibiotics are required to be stored between 15° to 25° C and other can be stored at ambient temperature. As the process of procurement and distribution will involve storage of drugs, the centres identified for storing such drugs should have requisite storage conditions as specified for each of the drugs being procured. These storage areas in addition should have temperature control and should also have proper pest control Programme in place. Otherwise some of the pests and rodents can damage the

quality of the drugs stocked. The infrastructure should also include proper stock maintenance through a computerized system and get inter linked with all the storage locations. This type of activity will help to cater to specific needs arising out of any outbreak of epidemic also to salvage stocks, which are nearing expiry. The data also helps to decide the purchase policy. The infrastructure should also include provisions for secondary packing in containers capable of protecting very high temperature during transit, particularly for thermo labile products. As a part of infrastructure requirements, qualified transporters having understanding and capabilities should be identified.

3. Procurement Policy :

The objective of procurement policy is to ensure that the drugs procured are of standard quality and are at competitive price. The procurement policy should also define the procedures to be adopted for procurement. The procurement policy should ensure that the drugs are procured directly from the manufacturers to the extent possible. The procurement policy should define the procedure for pre-qualification of suppliers based on the compliance to current good manufacturing practices requirements. It should also address primary testing of the drugs procured by notified agencies.

4. Evaluation of Manufacturers :

The quality of drugs produced by the manufacturers can be assured provided the firm is following principles of total quality management and adherence to current good manufacturing practice requirements. The evaluation of the installed capacity and financial capabilities to supply the drugs can be achieved through inspection of the facilities by a panel consisting of experts in the field. A proper grading system should be available which can be considered as one of the requirements for deciding the suppliers.

5. Procurement of Drugs :

A transparent mechanism should be created in procuring the drugs from the eligible manufacturers/ suppliers. A pre-inspection of the consignments at the manufacturers' level before supply should be made mandatory, as it will help proper evaluation of the supplies and will avoid rejections at the place of acceptance.

6. Distribution and Transfer of Drugs :

Based on the scientific estimation of requirements of each of the location in each State of the country, drugs need to be distributed through qualified transporters who understand the precautions to be taken during transportation. If the primary packing received from the supplier is not transport worthy, provision should be made to do a secondary packing in transport worthy packing.

7. Storage of Drugs :

Each of the locations where the drugs need to be stored should have proper storage conditions to store all categories of drugs which should include provision of deep freeze at minus 20° C, 2° to 8° C and air conditioned storage for storing below 25°C. Suitable racks/almirahs for storing the drugs at ambient temperature should be provided. The design of the warehouse should facilitate easy access and follow the principles of first in first out. The storage area should also have proper pest control and fire control to avoid any damage to the medicines procured.

8. Post Purchase Surveillance :

The quality of the drugs procured and distributed need to be evaluated through a well defined sampling procedure, post distribution, from hospitals. There must be a focus approach in such programmes as it will enhance the quality programmes and help to achieve the objective of supplying standard drugs to the people. Compilation of data from such surveillance will help at the time of reevaluation of the manufacturers/suppliers for supply of drugs.

Pharmacy Education And The Life Long Learner

Samsinah H Hussain
Associate Professor, Head, Department of Pharmacy
Faculty of Medicine, University of Malaya 50603
Kuala Lumpur, MALAYSIA

'Information is to be shared and education leads to empowerment!'

Information will remain stagnant if it is not utilized as knowledge for the betterment of mankind. Information will remain stale if it is not shared and practiced. With the dawning of the 21st century, the academia is required to be involved in global issues and relationships. This can only be achieved if information sharing takes place. Educators must consciously create an environment whereby lifelong learning can take place. For pharmacy educators, this is the challenge as new knowledge in pharmacy is expanding very fast and undergoing evolution. Students must therefore be taught to be able to learn and use information independently and not be dependent on a teacher. Learning methodologies must be developed and incorporated into the curriculum so as to be able to develop the student's ability to be a self-directed lifelong learner.

Furthermore, the education that a student receives in the university will affect the type of knowledge gained, the skills learned and also the attitude that is formed. With a dynamic curriculum, a lifelong learner can continue to contribute effectively to fulfilling the changing needs of the society toward the pharmacy profession.

Concurrent Changes in Pharmacy Education in Thailand : Striving to Survive Better

Sindhchai Keokitichai
Faculty of Pharmacy, Silpakorn University, Sanamchandr Palace Campus, Nakorn – pathom, 73000, Thailand

After over thousands of years of the development of pharmaceutical profession in the areas now called Thailand, movement of pharmaceutical learning and knowledge transfer has been changed dramatically, from the "closed / familial – taught system" to a more westernized system, since ca. 1820s. Pharmacy Education in Thailand has started with 3 – year Diploma Courses until ca. 1940 before moving to 4 – year (1940 – 1956) and 5 – year (1957 – present) courses respectively. However, changing trends of Pharmaceutical Education System in the United Stated of America and some other countries causes considerably great impacts on Pharmacy Practice in Thailand for over 30 years. This leads to challenging turning point in various aspects, academic and professional development alike. A 6 – year curriculum with a minimum 2,000 practice hours is under consideration of each Faculty to proceed.

There are now twelve Faculties of Pharmacy / Pharmaceutical Sciences in Thailand. Though we have formed "the Pharmaceutical Education Consortium of Thailand" since ca. 1978 to harmonize and standardize pharmacy, covering related sciences, curriculum in Thailand and to meet the international standard of quality assurance of Pharmacy Education and Professionalism, but due to the legislative autonomy of higher education system in Thai Universities, there are diverse differences among each individual Faculty. Even more complicated by Professional Roles, Functions and Responsibilities of Thai pharmacists, each Faculty can decide which directions they prefer to go for further development and that the Pharmacy Council of Thailand, a national governing body for pharmacy licensures, has no authority over the Faculty at all. Furthermore, Thai government has already imposed a strong policy for all public – funded universities to become autonomous chartered ones within ca. 2004 / 2005. This fundamental change will certainly affect Pharmacy Education as such. Every Faculty has essentially to strive and perform at its best in order to survive better. The strategic management for desired outcomes with its strategic and tactical master operational blueprints will decide the future of each school, more or less. Managerial Administration of both public – allocated and self – generating resources will play an important factor over institutional performance and outcomes. Nevertheless, all Thai schools of pharmacy still strongly have networking collaboration under competition.

Techno-Legal considerations in designing and defending an abbreviated New Drug Application [ANDA] – A Brief Insight

Umesh Banakar
Professor & President, Banakar Consulting Services 10251 Tammer Drive, Carmel, IN 46032 USA

An ANDA is a submission to the US-FDA, Office of Generic Drugs (OGD), for securing marketing authorization of a generic drug product of an active pharmaceutical ingredient. It is well known that generic products can be

marketed only after the patent for the innovator (drug substance and/or its formulation) has expired. To gain market advantage, not to mention the rush for first-to-file and thereby 6-month exclusivity, pharmaceutical companies (generic) are increasingly motivated to submit an ANDA before the expiration of the relevant patent, particularly for the pharmaceutical dosage form of a drug substance. In order to do so, the generic manufacturer is expected to submit a patent certification notice/noninfringing statement to the patent holder (innovator). In so doing, the generic company (technical staff as well as the in-house legal counsel) has to develop, design and defend the generic formulation which is supposedly a noninfringing formulation. Such a development and analysis of the generic product from technical standpoint, in addition to legal perspective, is essential, especially keeping the formulation development scientist in mind.

The presentation will present a brief introduction to the depth and the gravity of the importance of the techno-legal considerations in an ANDA submission. In particular, an understanding of some of the terminology commonly employed in such considerations, especially from scientists/ technical point of view will be presented. Additionally, some interpretations of patent claims and the discussions ensuing therefrom will be presented.

Perspective and Opportunities in Clinical Pharmacokinetics

M. Vasudevan
Director
Centre for Advanced Drugs Research & Testing (CADRAT)
JSS College of Pharmacy, Ootacamund, TN, India 643 001

The clinical research enables physicians and researchers to find new and better ways to understand, detect, control and treat illness. The "Clinical trial." . involves testing or studying of a drug or medical device in people. Clinical research for the New Chemical Entities (NCE) screening is an incredibly risky, laborious and high-cost process—only one in every 5,000 to 10,000 screened compounds eventually becomes an approved drug. The Clinical Research department focuses on clinical pharmacokinetics, Phase I and Phase II clinical trials on Investigational New Drugs - INDs, Phase III and IV clinical studies, bio-equivalence studies for generic drugs. The Unit has two independent functions namely, Planning and Execution of Preclinical, Phase-I, II, III & IV clinical studies and Clinical Pharmacokinetic studies.

Clinical Pharmacokinetics is one of the critical aspects in the process of a "chemical" becoming a "drug" by thoroughly understanding its kinetics i.e. the processes it passes through once administered in the body until the time it is excreted out. It is thus, study of ADME (absorption, distribution, metabolism, and excretion) of the drug. Major inputs for this come from animal kinetic studies carried out during the pre-clinical development. The process of planning for pharmacokinetics studies for NCE starts with identification of lead compound. Pharmacological / Toxicological evaluations have built in parameters for study of animal pharmacokinetics. This helps in finalizing the dose range for Phase-I studies. Thus, the actual study starts much later, in the process of drug development, the data generated all through help in defining the kinetic parameters the formulation must achieve.

Automation with combinatorial chemistry and high throughput ADME screening (HT-ADME) have accelerated the beginning stages of drug discovery. However, the impact on later stages has been put to pressure on the development team to quickly choose the best candidates to take into the clinic studies. Historically, odds of success in preclinical and clinical trials have been 1 in 10. Poor oral bioavailability is the primary reason for failure. That limited success is a huge drain on resources. The path of drug discovery and development proceeds from a therapeutic target. Screening for biological activity between the target and synthetic compounds and validation of that activity defines the hit to lead stage. The interface between discovery and development provides optimization of the lead for activity and availability namely, HT- ADME and physicochemical property evaluation (PCP). Full development, where candidates become NCE's (new chemical entities), covers the traditional areas of animal pharmacokinetics and toxicology and human clinical trials.

Compound attrition in discovery looks formidable but is enabled by HT - ADME. The big resource drain of time and money occurs in development with a 1/10 chance of success. However, the situation has improved with the early evaluation of compounds for HT- ADME and PCP and success probability is estimated to have improved to 1/6. In addition, if a candidate fails in Phase II or III clinical trials, as much as 10 years have been wasted on the overall discovery/development effort.

Clinical Pharmacokinetic studies on generic drugs in conformity with GCP/GLP guidelines, both for domestic as well as international regulatory requirements. Apart from requirements of regulatory submission, kinetic studies in smaller number of volunteers, is carried out as an on going activity for confirming the bio-availability of a new formulation.

TIFAC - Core in Herbal Drugs : A step towards need based education

M.J. Nanjan
Director, PG and Research Studies
J.S.S. College of Pharmacy, Ootacamund 643 001

In recent years, there has been great demand for plant-derived products in developed countries. These products are increasingly being sought out as medicinal products, neutriceuticals and cosmetics. The world market for these products has been estimated to be Rs.67, 000 crores and this is growing at a rate of 15% per annum. India's share is only 4200 crores, in spite of the fact that, India has one of the 12 mega biodiversities in the world. One of the major reasons for India's poor performance is that our products are not backed by rigorous scientific studies to establish their safety, efficacy and standards. There is thus, a need to initiate activities in this direction to take India to the world leadership. With this in view the TIFAC centre of Relevance and Excellence (CORE) was established at J.S.S. College of Pharmacy, Ootacamund, which is one of the leading institutions in India, imparting quality pharmaceutical education at diploma, degree, post-graduate an doctoral levels. With the support of Technology Information, Forecasting and Assessment Council (TIFAC), an autonomous council of the Department of Science and Technology, Govt. of India and Pharmaceutical industries, the centre has been functioning for the past nearly 3 years. The CORE has been functioning with the objectives of conducting M.Pharm., and Ph.D., programme in Phytopharmacy and Phytomedicine to cater to the manpower needs of pharmaceutical industries engaged in herbal products, conducting continuing education programs for the benefit of herbal industries, undertaking research in the area of scientifically validated herbal drugs and their standardization, interacting with pharmaceutical industries engaged in herbal products to solve their specific problems and documenting the traditional medical practices and the medicinal plants of India so as to protect them from piracy.

Recent Developments in Antibacterial Oxazolidinones

Shiv Kumar Agarwal
Vice-President, Orchid Chemicals & Pharmaceuticals Ltd.
R&D Centre, Sholinganallur, Chennai 600 119

Significant research effort continues towards the development and marketing of novel antibacterial agents. Since the discovery of penicillin, pharmaceutical industries have produced number of synthetic or semisynthetic antibacterial agents to combat a wide variety of bacterial infections. The major classes of antibacterial agents are β-lactams (including, penicillins, cephalosporins, monobactams, carbapenems), sulfonamides, tetracyclins, aminoglycosides, quinolones, macrolides and glycopeptides (e.g. vancomycin and teicoplanin). However, in the past several years, extensive use or/and misuse of these antibacterials has generated the rapid emergence of bacterial resistance.

Many promising compounds are being identified from previously described classes such as Quinolones, Oxazolidinones, Macrolides, Cephalosporins and Carbapenems. In addition, new approaches based on adjunct therapy and novel target inhibition have emerged, in part due to the impact that genomics is starting to have on the antibacterial research field.

In recent years, the most significant problem in clinical practice for the treatment of bacterial infections is the increase in the isolation of methicillin resistant Staphylococcus aureus (MRSA), methicillin resistant Staphylococcus epidermidis (MRSE), quinolone resistant Staphylococcus aureus (QRSA), vancomycin resistant enterococci (VRE) and multi resistant M. tuberculosis (MDRTB) strains.

In 1978 Dupont, demonstrated a series of oxazolidinones have in vitro antibacterial activity against human pathogens. As the result of a continuous investigations on these series of the compounds, oxazolidinone derivatives Dup 721 and Dup 105 are orally active and showed potent in vitro and in vivo antibacterial activity against

Gram positive pathogens including MRSA and MRSE as well as anaerobes and Mycobacterium tuberculosis. In 1987, Dup 721 was selected as an antibacterial new candidate for clinical trials. However, further development was discontinued due to toxicity observed in phase I clinical trials. After that, Pharmacia & Upjohn disclosed several new oxazolidinones including Linezolid and Eperezolid. Later many companies reported several oxazolidinones modifying substituents attached at the mitrogen atom of oxazolidimone nucleus with a variety of heterocyclic compounds.

The first compound in this class, Linezolid was launched in 2000 in United States but within a short period of time resistant strains have been reported. Linezolid is a bacteriostatic against most susceptible organisms but displays bactericidal activity against some trains of pneumococci, Bacteroides fragilis and C. perfringens. Linezolid acts by inhibiting the initiation of bacterial protein synthesis. Cross-resistance between linezolid and other inhibitors of protein synthesis has not been demonstrated.

Recent developments in antibacterial Oxazolidinones and their Structure activity relationship shall be discussed.

Trends in Pharmacy Education in Japan - A new 6-year curriculum on the Horizon

Motoko Kanke
Professor, Kyoritsu University of Pharmacy, Tokyo, Japan

Since the end of WWII, pharmacy education in Japan has been structured around organic chemistry. This discipline along with the synthesis and manufacturing of pharmaceuticals were the top priorities in the pharmaceutical industry in post-war Japan. With the rapid progress of medical technology and the development of new pharmaceuticals, these two factors heralded the call for a renovation of the educational system to educate students to become expert pharmacists as well as pharmaceutical scientists and researchers. The students and graduates of today are not only required to learn advanced topics and gain an expertise in specific professional areas but also to cope with a near explosion of information and corporate globalization. In response to these presing needs, most scholls of pharmacy attempted to meet this challenge by upgrading their educational orrerings, but the ranges were minimal.

In 2001, a task force was appointed by the Pharmaceutical Society of Japan to study pharmacy curricula throughout the nation. As one of its charges, a model core curriculum for all schools of pharmacy was unveiled in 2003. The proposed curriculum incorporates a practical, on-site educational program and a research training program that requires a thesis before graduation. The major goals of the proposal are to (1) educate students to become expert pharmacists and pharmaceutical researchers who meet the needs of society, (2) guide students so they can chart their own professional pathway, (3) evaluate student achievements objectively, (4) offer a balanced curriculum in the basic and clinical sciences and (5) always ensure adequate experiential programs for both the on-site clinical pharmacy and research training components.

In addition to basic and advanced pharmacy subjects, the proposed curriculum would also include an exposure to the liberal arts to broaden a student's perspective of life and the world. Since the model core curriculum is expected to serve as a guideline, each school would still have the flexibility to develop their own unique curriculum and one that would reflect their individual academic strengths.

We are confident that the Japanese deit (Congress) will approve passage of a proposal, effective in either 2007 or 2008, that will increase the matriculation time in pharmacy school to six total years. What remains to be decided is whether these six years will go straight through as an undergraduate program or be segmented into four yars of an undergraduate program plus an additional two years of a graduated program. We will make this decision very soon.

Harmonization of Pharmacy Education

B.G. Nagavi
Professor, Principal, JSS College of Pharmacy, Mysore

Globalization and free trade options in the last few years have opened-up international markets not only to business but also to education. Universities are opening there branches in different parts of the globe and offering various courses. Pharmacy Education is no exception to this. Globalization of Pharmacy education is a reality, as it

is a world phenomenon. Pharmacy Education is offered in most of the countries. Various courses such as Pharmacy Technician, Diploma, Degree, Post-graduation and Research in Pharmacy are conducted through full time, part-time, on campus and off-campus and flexible learning modes.

Today Patients, Pharmacists and Drugs are mobile and can reach every place from any place on the globe. Globalization is bound to develop further. Internet marketing, e-prescribing and e-learning are moving at amazing speed. Education has to imbibe all these changes for its own survival.

There is a need to Harmonize Pharmacy Education and to have broad conformity in education in the areas of content and evaluation, in order to provide graduates and post-graduates acceptable in different parts of the globe. Due to increase in mobility by air and communication revolution through mobile and internet, people travel across the globe very freely and frequently for education, job and settlement. Since, Pharmacists are also very mobile, harmonization of education with respect to content, types of courses offered, competencies, practical skills to be acquired, communication skills etc. have to be broadly standardized and agreed upon. We may begin this initially in the South East Asian, Asian or SAARC regions. Federation of Asian Pharmacy Associations (FAPA) and other bodies can play key role in the harmonization process. Ways and means of the harmonization process will be discussed.

Drug utilization studies using ATC / DDD Methodology

Bruno Louis
Senior Clinical Pharmacist, Department of Pharmacy
Sultan Qat University Hospital, Al Khod, Muscat, Oman

World health organization (WHO) defined drug utilization as the "marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences". Drug utilization studies (DUS) can be quantitative or qualitative. The quantitative study quantifies the present state and trends of drug usage at various levels in a health care system, while qualitative study assess the appropriateness of drug utilization in relation to drug prescribing.

If DUS ae to be reliable and useful it should follow standard methodologies agreed by international bodies. The most important is the use of a common drug classification system and an international unit of measurement. The Anatomical-Therapeutic-Chemical (ATC) classification system was developed in Nordic countries and later adopted by WHO for drug use studies. In ATC classification system, drugs are first divided into different groups according to the organ or system on which they act and then their pharmacological and therapeutic properties and finally their approved chemical names. The international unit of measurement is the defined daily dose (DDD), which is the assumed average maintenance dose per day for a drug used for its main indication. The utilization of a drug in a given geographical area can be expressed in DDD per 1000 inhabitants per day, where as in hospital setting it is expressed as DDD per 100 bed days. The ATC/DDD system allows standardization of drug groupings and a stable drug utilization measure to enable comparisons of drug use between countries, regions and other health care settings and to examine trends in drug use over time and in different setting.

In 1996, WHO recognised the need to develop use of the ATC/DDD system as an international standard for drug utilization studies. The methodology has demonstrated its suitability in drug use research and is being used by an increasing number of researchers worldwide. Drug utilization data can be used to monitor the effect of drug regulatory activities and for intervention to improve prescribing and drug use. It will identify areas of possible over or under utilization and as a marker for crude estimate of disease prevalence. This methodology is also being used to investigate the utilization of antibiotic in hospitals and countries and creating comparble monitoring systems for cross-national antibacterial utilization patterns in the work against bacterial resistance. We have used this methodology to study the utilization pattern of antibiotics and evaluated the impact of restrictive policies on their usage. Presently we are studying the relationship between the volume of antibiotic use and emergence of resistance. The benefits and limitations ATC/DDD methodology need to be clearly understood while using theis method. From a national health policy perspective DUS will provide sound scientific evidence for making policy decisions.

Pharmacy Education in the Philippines

Olivia M. Limuaco
Dean, School of Pharmacy
Centro Escolar University, Manila, Philippines

Pharmacy practice worldwide has been more patient-focused rather than drug-focused brought about by tremendous changes in Health Care Delivery System. However, in the Philippines, the needed change takes time due to some barriers. Despite such difficulty encountered, the PACOP has embarked on providing series of continuing education for faculty members geared toward more patient focused pharmacy education and practice.

Formation of Drug Nanoparticles and Microparticles using Supercritical Fluids

Ram B. Gupta
Department of Chemical Engineering
Auburn University, Auburn, AL 36849-5127, USA

Supercritical fluids are now being used to form particles of various materials. Supercritical water (>374.2 °C, >220.5 bar) is used to form nanoparticles of inorganic compounds, whereas supercritical carbon dioxide (>31.1 °C, >73.8 bar) is used to form micro- and nano-particles of mostly organic compounds. Major advantages with these technologies are the environmentally benign & single step process, and clean product. Due to the great interest in these technologies, research & industrial activities have grown considerably.

Compounds that are soluble to some extent in supercritical carbon dioxide (e.g., naphthalene, lovastin, naproxen, griseofulvin) can be precipitated as nanoparticles by rapid expansion of the supercritical solution (RESS).

RESS Process : *On the other hand, compounds that are highly insoluble in supercritical CO_2 (e.g., PLGA, PLA, insulin, lysozyme, trypsin, tetracycline, budesonide) are first dissolved in a suitable solvent (e.g., methanol, methylene chloride, toluene, THF, DMSO, DMF), then the solution is injected in the supercritical CO_2 antisolvent (SAS), precipitating the compound as microparticles.*

SAS Process : *SAS is the most popular method of particle formation for pharmaceutical applications.*

Particles of pure pharmaceutics as well as in polymer encapsulated formed can be prepared (e.g., PLA/naproxen, PLA/gentamycin, PLA/rifampin, PLGA/estriol, PLGA/BSA) for control release applications. Though organic solvents such as DMSO alter the structure of proteins such as insulin, lysozyme, trypsin; fortunately, the proteins recover their biological activity upon reconstitution with water.

A variation of SAS process is the PCA process in which antisolvent fluid is injected into the liquid solution, to obtain larger microparticles, mostly of polymer containing formulations.

PCA Process : *Another variation of SAS process is solution-enhanced dispersion by supercritical fluids (SEDS) process in which solvent and antisolvent flow in a coaxial nozzle and meet at the tip. With this method particles of labile biological compounds (e.g., proteins, enzymes, DNA) dissolved in water have been formed. A small amount of cosolvent (e.g., methanol, ethanol) in supercritical CO_2 is used to extract water from the solution. Also the contact between organic solvent and labile biomaterial is only for a brief time period, minimizing denaturation of the solute.*

SEDS Process : *Using SEDS process, the crystalline polymorph of the obtained particles can be controlled by operating in different regions of supercritical phase. For example, pure forms of two salmeterol xinafoate polymorphs have been prepared by SEDS technique*

There have been numerous studies using SAS-based processes on the variation of the process parameters such as pre-expansion pressure, temperature, nozzle geometry, density of antisolvent, flowrate and concentration. But the control on the particle size has been minor, and it still cannot produce fine particles in the sub-micron range (<300 nm) for soft materials. Recently, Gupta's research group has developed supercritical antisolvent with enhanced mass transfer (SAS-EM) process, which shows a much better control on the particle size and morphology. Particles of controllable size and up to ten-fold smaller with a narrower size distribution are obtained. Like the conventional SAS technique, the new technique SAS-EM also utilizes supercritical carbon dioxide as the antisolvent with a simple nozzle, but in this case the solution jet is deflected by a surface vibrating at an ultrasonic frequency, that atomizes the jet into much smaller droplets. Furthermore, the ultrasound field generated by the

vibrating surface enhances mass transfer and prevents agglomeration through increased mixing. The particle size is easily controlled by varying the vibration intensity of the deflecting surface, which can be adjusted by changing the power supplied to the attached ultrasound transducer. This new technique has been demonstrated for nanoparticles of different pharmaceuticals including lysozyme, tetracycline and griseofulvin.

SAS-EM Process : It is easy to satisfy GMP requirements with supercritical fluid based particles production since the process is totally enclosed and usually require only a single step. SAS-EM process has been scaled up by Thar Technologies, which can produce up to 1 kg/day of nanoparticles, with automated control and continuous collection.

Commercial SAS-EM Unit by Thar Technologies (www.thartech.com)

Community Pharmacy In India-A Practical Approach

R Srinivasan
Member, Community Pharmacy Division IPA and
Chairman CPD of IPA Tamilnadu Branch

If there is one industry that has the potential to replicate the Indian software success story globally, it is pharma. .So many things are happening- Bio-technology, the human genome project, genetic mapping, new drug discovery.. Is Indian pharmacist aware of the future challenges, changes, opportunities ? Unfortunately Pharmacy practices in India has not been recognized as an integral part of the emerging Pharmaceutical challenges and the attention it requires to prepare them to play their role as resourceful Community Pharmacists. This paradoxical situation has to be corrected before it is late.

There is a misconception that in India all medicines, including those falling under Schedule H of the drugs & cosmetics Act are freely sold over the counter by Pharmacists without prescriptions. In most of the developed countries the system clearly defines the role of physicians prescribing and the pharmacists dispensing, while in India the functions are overlapping mostly in rural areas. There are unqualified Doctors in rural areas and qualified doctors prescribe and dispense medicines in their clinics not only to their patients but others too, while there are Pharmacists recommend and dispense medicines to the patients mostly for common ailments. "Historically, the GP and community pharmacist have a common ancestor in the apothecary, an adviser on health and dispenser of medicines". 1.

Merely comparing the pharmacy practices in developed countries and prevailing practices in India without considering certain realities will be a subjective assessment. We have to take an objective approach to change this situation.

The necessity to improve the Pharmacy practices on professional scales cannot be ignored nor delayed in the context of emerging changes, when India is becoming a fast developing nation in the world. This calls for innovative marketing dynamics in every industrial activity. In Pharmaceuticals as a health care Industry. India has already proved its technical competence and capabilities by producing basic drugs and formulations, in every therapeutic segments including preventive medicines for both domestic and global markets. By 2005 Indian drug manufacturers are expected to become major exporters to European countries and in USA, in generics.

This major transformation in R&D, production, marketing etc., however, has not penetrated down the line, the vital link in supply chain i.e. the pharmaceutical Trade. Ensuring the quality of medicines till they reach the consumers is as vital as GMP. A well defined distribution practice right from warehousing, transportation, proper storage, handling and dispensing at the retail counters is therefore a logical extension GMP in Supply Chain.. In this chain- the ultimate and vital link is Community Pharmacy. The need to redefine the pharmacy practices is precisely what we have to focus and as the core issue and in the interest of the customers..

Let us now, analyze the India specific pharmaceutical care with its unique paradoxical environment.

Size of population, second largest in world next to China; vast rural and micro interior penetration required to take the health care needs to the rural and urban masses- these are to be viewed from some of the peculiar situations as listed below:

Illiterate rural masses	vs. educated enlightened consumers
Non availability of basic health care	vs. emerging quality medical care in urban centres

Quackery practice in rural areas	vs. highly competent medical profession
Vast number of drug stores/medical	vs. awareness to develop professional pharmacies shops
Non availability of pharmacists	vs large turnout of qualified pharmacists
Small/ tiny sectors in pharma mfg	vs large scale Indian/MNC mfrs
Weak regulatory agencies in	vs efficient State level Drug control machinery some States

We can add several such contradictory factors but cannot escape from the necessity to look forward to improve the quality in pharmacy practices. Otherwise there we will be helplessly witnessing an impressive growth of pharmaceutical Industry vs. outdated, unskilled medicine dealers defeating the very purpose of making the quality medicines available to the public with professional care and advice.

Role of Professional & trade Associations: In this context it is crucial that we take bold initiative to educate the practicing pharmacists, change their mind set and prepare them as Community Pharmacists by introducing refresher courses at State and district Head quarters with a time frame.

Scope for training:

Everyday, pharmacist is asked by customers for advice about minor ailments. The may require advice on symptoms; may ask for a medicine by brand name; may require general health advice e.g. about dietary supplements, precautions etc

"The pharmacist's role in responding to symptoms and overseeing the sale of over-the-counter (OTC) medicines is substantial and requires a mix of knowledge and skills in the area of diseases and their trteatment"2

Basic knowledge about the drugs and diseases: In the ever growing OTC segments of products, lay press advertisements, self medication, drug abuse, non-compliance of dosage regimen, mixing of OTC medicines with prescription medicines; changing life style and food habits' prevalence of diseases like asthma, tuberculosis, diabetes etc, there is need to educate and advice the consumes on proper and safe use of medicines- and it requires regular refresher courses to prepare the community pharmacists in patient care and counseling.

With the advent of IT, a wealth of information is available thru web-sites and Drug Information Centers on Drugs, their actions, indications, side effects etc. Community pharmacists must provide a computer in their Pharmacies for access to all these information thru inter-net and most essential is to maintain a patients profile for their regular customers, specimen of Community Pharmacy Medication record* recommended is given below:

Patient name

Address Physician:

Age Telephone number

Sex M/F

Phone Number

Allergies

Medication Record

Date Rx no Physician Drug & Strength Quantity Sig/dosage Refills

Pharmacists' notes & other patient Information

Eg:

Date Comment: OTC drugs dispensed/used

2 Need to maintain proper statutory records: It is in the interest of pharmacists that they buy the medicines from authorized sources with proper purchase records. Maintain sales memos with patients name and address, batch number of the medicines sold, as a legal requirement and to safeguard themselves in the event of any drug found sub-standard or unsafe requiring recall etc.

3 Need to provide patient information brochures: Pharmaceutical Associations, Manufacturers can provide brochures to be distributed to patients at the Counters on disease like Asthma. Diabetes, hypertension, epilepsy even common cold and cough, with Dos and DONTs etc,.

4 To provide information for Immunization and if space permits, vaccination programs can be organized with the help of manufacturers in the Pharmacies.

5 Geriatric care: Elderly patients tend to get confused or forget to take medicines properly. Complementary packs for keeping each medication separately with dosage marked will help them to take medicines as prescribed.

6 *Need to provide basic monitoring/test devices in the Pharmacy: In the counseling area Pharmacists can provide B P apparatus, devices are available to test blood sugar etc*

7 *Proper Storage:: All medicines are temperature sensitive and to retain their potency and efficacy proper storage is essential, protected from sunlight and heat. While it is recommended that all Community Pharmacies are air conditioned, there is a proposal to amend D&C Rules to provide air conditioners compulsorily.*

8 *Access to Drug Information centres/ reference books/ web-sites on drug information: This is possible by providing Computers and Inter-net connectivity.*

9 *To develop communication skills: As Pharmacists, to understand customer needs, it is necessary to develop listening skills, questioning skills. *2*

10 *To develop a positive mind set for ethical pharmacy practices, evolving all professional, legal and moral obligations to the society.*

These should be basic parameters on which we must introduce a practical approach to Community pharmacy environment in India .Community Pharmacy Division of IPA with All India Organization of Chemists & Druggists with State Pharmacy Councils as nodal centres, can organize jointly, structured programs to train practicing pharmacists in every major towns so that before 2005, we can bring a perceptible change in pharmacy practices in India.

As a supplementary activity, a Journal dedicated to Community Pharmacy is necessary to constantly update their knowledge on new molecules, and this should reach all leading pharmacies in India. Such professional Journals can be sponsored by manufacturers.

Implementing NIR Methods for Raw Material Inspection

Richard W. Streamer
Asia-Pacific Regional Manager, Foss NIRS Systems, USA

Near infrared Spectroscopy (NIR) is a simple, quick, non-destructive technique that provides multi constituent analysis on virtually any matrix with levels of accuracy and precision that are comparable to conventional analytical methods. NIR analyses require no sample preparation and no reagents. With the help of statistical techniques (chemometrics), modern NIR instrumentation can be implemented for qualitative and quantitative analysis Offline, At-line or In-line.

In the pharmaceutical industry, NIR methods of analysis have been successfully implemented for more than 10 years. All major multinational pharmaceutical companies have implemented NIR, in some form, across all their manufacturing locations.

With growing regulatory expectations of 100 % inspection of all incoming raw materials, the NIR offers rapid, sensitive, precise & cost effective measurements. Over 70% of the NIR units in the field are doing some form of Raw material analysis

The instrument's robustness, ease of operation and method transferability has seen large numbers of systems implemented in the warehouse, dispensary or Q.C. laboratory.

Applications of NIR have been mainly focused on the inspection of raw materials, excipients, packaging materials and solvents. More recently, attention has turned to real time information for control of various manufacturing operations like blend uniformity, drying, analyzing solid and liquid formulations for product quality, chemical production processes and solvent recovery systems.

USP, EMEA and PASG have released guidelines for NIR method development and validation. Recently US-FDA has released draft guidelines on Process analytical Technology (PAT), which recommends real time tools like NIR for monitoring and control of pharmaceutical processes.

Post Approval changes to DMF, ANDA & MAAs in US & EU and Change Control Management

Vivek Kapur
Group Leader, International Drug Regulatory Affairs
Ranbaxy Laboratories Limited, A-10 Phase 3 Industrial Area
SAS Nagar (Mohali), Punjab 160055, India

Changes to an approved Drug Master File (DMF) for active pharmaceutical ingredients (APIs), Abbreviated New Drug Application (ANDA) of a dosage form in the United States(US) and Marketing authorization applications (MAA) of a dosage form in the European Union (EU) constitute a

very major and important part of regulatory affairs function in pharmaceutical organizations dealing in regulated markets like US & EU.

The urgencies and speed needed at the time of filing (such as from a pilot plant) and changes needed by manufacturing and quality control at the time of commercialization of the product trigger the need for notifying/ filing changes to regulatory agencies as an Annual upate (in US), changes being effected (CBEs in US) / Type I variations (In EU) or Prior approval supplement (PAS in US) / Type II variations (in EU).

Although in an ideal scenario, commercial manufacturing should immediately follow an approval, in many instances it becomes paramaount to apply for changes in the filings to ensure compliance to all the regulatory commitments and facilitate commercial and manufacturing needs of the product. This may be as a result of commitment s made during the approval process e.g. Mutual Recognition Procedure (MRP) in the EU (e.g. changes to tablet shape needed by a particular EU country) or assisting manufacturing need (e.g. change in batch size of the product)

Guidelines provided by US FDA e.g. BACPAC (Bulk Actives Post Approval Changes), SUPAC (Scale-up Post Approval changes) & changes to approved NDA and ANDAs, and European Commission notice to applicant (Guideline on dossier requirements for Type IA and Type IB notificatios) will be discussed.

The presentation aims at bringing a harmony in the understanding on managing post approval changes in regualted markets of US cersus EU, and notifying the regulatory agencies accordingly, in order to comply to the regulatory requirements for these markets. The documentation requirements for various categories of post approval change filings will be discussed.

Globalization of Indian Pharmacist where we are? Where we should be going?

Prafull D. Sheth
President, Indian Pharmaceutical Association

These are the times when major strategic changes are taking place in the way and manner in which health care delivery is being sgaped. These changes require a corresponding reorientation in professional training and practice in the profession of pharmacy in India.

The World Gealth Report 2000 highlighted the key contributions of health systems to improve health worldwide. Human resources are at the heart of the health system. Globalization of Indian Pharmacist in the context of where they are and where they should be goind is an imperative and requires thorough examination.

During the 55th World Assembly in May 2002, Dr. Gro Harlem Buntdtland, WHO, DG, described an initiative to improve human resources in national health systems. Furthermore at the 55th World Health Assembly, countries asked WHO for sound national policies and straegies to accelerate development of an action plant to address the ethical recruitment and distribution of skilled healthcare personnel and the need for their training and management. In 2005, at the UN Millenium Summit world leaders agreed to set time-bound and measurable Millenium Development Goals (MDGs) which requests countries to improve certain basic standards of life for everyone by 2015. But unless all human resources for health - pharmacist included - perform, the Nobel mission of achievement of MDGs will remain a moving target.

As per International Forum on Medicines (IFoM) an international think tank established by International Pharmaceutical Federation (FIP), the gap between the demand for medicines and available health budgets will increase. The pace of novel drug development, wider definition of "treatable" disease, shift from short term to long term treatments, aging of the population and an increasingly empowered and demanding patient population will be crucial cost drivers, In the emerging scenario, pharmacist should adapt themselves and enhance the quality of drug therapy by identifying inappropriate prescribing, pharmaceutical delivery, patient compliance, patient idiosyncrasy and appropriate monitoring of drug therapy.

Countries national drug policies suggest that pharmaceutical issues, and by implication pharmacists, are on the public health agenda. But it is sad to note that in many countries pharmacy was not being accorded its rightful place in the health budgets, It is rather frustrating to note that in India, national health policies like promotion of essential drugs, health for all, primary health care, HIV/AIDS, TB, Malaria, or population are not related directly or otherewise to pharmacists.

As far back as 1988, a report of the WHO Consultative Group in New Delhi concluded that only when pharmacist has been accepted as vital member of the health care team thus can necessary supporting services be orgainzed with the professionalism that they demand. While many countries took advantage, on the hind site, I wonder whether we may not have missed opportunity in educating our decision makers to cash in on such an important document? While Ministry of Health usually endorses the World Health Assembly resolutions, the Indian Govt. has conveniently avoided implementation and inclusion of pharmacy in the national health policy.

Mr. Murtada M. Sesay, Immediate Past President, CPA while delivering B.V. Patel Memorial Lecture at the 8th CPA Conference in Jamaica State that late Shri B.V. Patel, Former President of the Indian Pharmaceutical Association and Founder Member of CPA rendered valuable services especially in the development of pharmaceutical legislations within Commonwealth countries. It would be a fitting tribute to put in place some mechanism and bring about changes in the national health policies to develop a relevant Indian global pharmacist. Simultaneously, the leadership in the statutory bodies should look ahead and create a fit between appropriate education and training in contemporary pharmacy practice.

Value - Crisis in Higher Education : Causes and Remedies

C.K. Kokate
Vice-Chancellor, Kakatiya University, Warangal 506 009

A review of the planning experience of the past five decades in our country reveals the broad limitations of the "top-down" or "trickle-down" approaches to educational development. To improve the effectiveness of various programs phased out to help different strata of society, the institutions of higher learning must be reoriented to capture and internalize the aspirations of the common man and suitably modify them, consistent with the resource availability and the existing institutional infrastructure. Building and sustaining the magnetism necessary to attract and shape the grass roots educationists of the country certainly, requires a dynamic and strategic planning of higher education.

A necessary concomitant of globalization of economy is the globalization of education. Weightless capital (knowledge) is supplanting the physical capital as a source of present and future growth. Globalization of education should be perceived, not as a threat but,as an opoortunity. This opportunity has to be grabbed, as early as possible. Institutions of higher learning must create exportable quality knowledge - the potable knowledge.

Industry-University interaction is of paramount importance, if both are to survive. It is necessary to establish incubation centres in universities, where there exists knowledge base and innovations that have potential for commercial application. This will help in strengthening university-industry ties and overcoming problems like resource crunch, and irrelevance of academic efforts. Further, it encourages freedom to faculty in research pursuits and upgradation of technology in industry. Universities cannot exist any more in isolation. There should be a close liaison between universities and industry in the fields of Research and Development and continuing education. It is necessary to demad, impose and implement global quality standards of research, make a commitment to nurture both education and research on a long term basis and develop a highly competitive and responive research community and industrially relevant trained manpower capable of meeting challenges of Post-GATT era.

Monitoring Adverse Drug Reactions

C.J. Shishoo
8, Shivalaya, Gulbhai Tekra, Ahmedabad 380 006

Modern drugs can save lives but if not used carefully they can take lives. Only a drug that is effective, safe and economical should be used in therapy.

According to an important study conducted by the Institute of Medicine, an independent and prestigious group that advises the US Government on health policy, each year drugs kill atleast 14000 hospital patients and another 750,000 people become sick and have to seek medical attention or seek admission to a hospital, due to side effects of drugs, misdiagnosis, bad prescribing, improper dispensing or, irrational use of drugs.

Modern drugs are very potent and pose the greatest risk because the full extent of the adverse drug reactions (ADR) does not come to light until they have been used by a large population of patients for atleast a few years.

Since 1993, seven drugs approved by US-FDA have been withdrawn after reports of death and severe side effects. These drugs were cited as suspects in atleast 1002 deaths. The actual number of deaths and morbidity could be much higher. Sibutramin, Troglitazone, Cisapride, Cerivastatin, are some of the drugs that have been withdrawn after being used for a few years. Recently, European Medicine Evaluation Agency (EMEA) has banned the use of numesulide in children below the age of 12 years in all member countries. The drug, however, continues to be used in India to treat pain and fever in children.

In India, 70% of the practicing doctors have been trained in non-allopathic medicine. For many medical practitioners, the main source of information about the drugs, their usage and their ADR are the medical representatives who are essentially promoting their our drug products.

What is more alarming is the non-existent Patient Information Leaflets for Indian patients. Information to patients about the drug prescribed - correct dosage, drug-drug and drug-food interaction and more so its adverse effects - is not made available by a drug manufacturer. All that he is advised is "for more information consult your doctor".

India has yet to establish a central facility to record ADR data. The ADR data must be obtained from the practicing doctors, hospitals, health care professionals and must be collected, analysed and collated. Otherwise, the patients find themselves at the receiving end.

Facing International GMP Audits effectively

Atul Shirgaonkar
Course Director, Insight Systems, Inc., Pune

Manufacturing and marketing authorisations are provided to firms to produce medicinal products of right quality standards. It is virtually impossible to maintain right quality standards without GMP compliance and therefore monitoring of GMP compliance on a regular basis is an important measure of attainment of quality objective of any organisation. To attain these objectives, one has to face GMP audits from international regulatory agencies, particularly if the products are intended to move into international markets.

An audit is defined as "A planned and systematic examination and check of a system, procedure or operation in order to monitor compliance with and the effectiveness of established standards and to allow for improvement and corrective measures where required. "This means - the Auditors basic objective is to :

Perform a documented independent inspection and review of a quality system;

To verify, by examination and evaluation of objective evidence, the actual degree of compliance with those elements of the quality system under review and that adequate controls are in place;

To ensure that the manufacturer provides a safe pure and effective drug product / drug substance by examining the objective evidence;

To assure that company quality goals will be routinely met and to comply with the GMP regulations, measure the effectiveness of the quality system by assuring that the products and processes conform with specifications.

This therefore involves understanding the three Ps of handling international GMP audits successfully i.e. Plan (think in advance about the GMP requirements), Prepare (execute the plan) and present (face to face with the auditor) which shall be discussed in greater detail during the plenary lecture.

Quality Assurance of Medicines through Good Distribution Practices - The Eu Guidance

Atul Shirgaonkar
Course Director, Insight Systems, Inc., Pune

Due to stringent controls on the manufacture of medicines, it is assured that the medicines are SAFE, PURE AND EFFECTIVE. This philosophy gets extended even to the

distribution of medicines to the sellers (wholesalers and retailers) of the medicine and ultimately for the benefit of the patients. The EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/ 03) cover in detail the QA system involved in the distribution of medicines, they however do not cover commercial relationship between parties involved in distribution of medicinal products nor questions of safety at work..

The Principle of GDP in as follows

The Community pharmaceutical industry operates at a high level of quality assurance, achieving its pharmaceutical quality objectives by observing Good Manufacturing Practice to manufacture medicinal products which must then be authorised for marketing. This policy ensures that products released for distribution are of the appropriate quality. This level of quality should be maintained throughout the distribution network so that authorised medicinal products are distributed to retail pharmacists and other persons entitled to sell medicinal products to the general public without any alteration of their properties.

The quality system operated by distributors (wholesalers) of medicinal products should ensure that medicinal products that they distribute are authorised in accordance with Community legislation, that storage conditions are observed at all times, including during transportation, that contamination from or of other products is avoided, that an adequate turnover of the stored medicinal products takes place and that products are stored in appropriately safe and secure areas. In addition to this, the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period. A tracing system should enable any faulty product to be found and there should be an effective recall procedure.

GDP encompasses QMS in relation with Personnel, documentation and records, procedures, premises and equipment, delivery and return systems, emergency plan and recalls and dealing with counterfeit medicinal products. This is ultimately for the well being of the community that relies on quality medicines. All these details shall be discussed during the symposium.

Identification and Characterization of diagnostically relevant major epitope of A. fumigatus

S.B. Katti
Medicinal Chemistry Division
Central Drug Research Institute, Lucknow 226 001

Allergic bronchopulmonary aspergillosis (ABPA), an immunologicall complex allergic disorder, is caused by the fungal pathogen Aspergillus fumigatus (Afus). Detection of elevated levels of specific IgE and IgG antibodies in the sear of ABPA patients is one of the important criteria for immunodiagnosis. A sensitive, specific and standardised immunodiagnostic assay is not available due to lack of well-defined, purified, specific, immunodominant antigens. The present study was carried out to identify and evaluate immunodiagnostic relevance of synthetic epitopic peptides of Asp f I, a major allergen/antigen/cytotoxin of Afu. Five overlapping peptides corresponding to the N-terminal of Asp f I, the immunodominant region predicted by twelve algorithmic programmes were synthesised. One of the peptides (P1) significantly inhibited IgG binding (89.10 ± 4.45 %) and IgE binding (77.32 ± 3.38%) of the standardised diagnostic antigen, SDA (well-defined pool of diagnostically relevant allergens/antigens of Afu). By using a panel of sera from 20 ABPA patients, 20 allergic patients with skin test negativity to Afu and 25 healthy individuals, P1 was observed to perform with a higher diagnostic efficieny in an enzyme linked immunosorbent assay for specific IgG (100%) and IgE (98.3%) antibodies than SDA. The diagnostic effciency of P1 could be attributed to presence of IgG and IgE binding epitopes similar to P1 in various immunodominant allergens/antigens of Afu. In view of its high diagnostic value and its nature as a well-defined reproducible allergen/antigen, Pi could be useful for development of a standard, specific and sensitive immunodiagnostic test for aspergillosis. Design, synthesis and diagnostic relevance of one of the peptides will be presented.

Clinical Research - An Emerging Opportunity for Pharmacist

Adeep Bagati
Vice-President, R&D, Cadila Pharmaceuticals Ltd, Ahmedabad

"I have always known, that at last, I would take this role, but yesterday, I did not know that it would be today"

A quote by Narihira as old as 1000 years seems to be very true for the clinical research in today's India.

The Pharma industry has witnessed a significant growth especially in clinical research, which reflects a trend towards globalization. Global pharmaceutical industries experienced delay in the development of new products due to unsatisfactory patient recruitment rates and the cost of clinical development which is two third of the entire developmental cost. This has led them to explore destinations like Latin America, Eastern Europe, Commonwealth of Independent states (CIS) countries and Asia. However amongst the Asian countries, India stands out prominently due to patient population, English-speaking doctors, and huge pool of treatment naïve patients who are willing to participate in clinical studies and the professionals who can be trained and hired for the clinical research. On the other hand, at the global level, 14% of R&D is being outsourced, 22% of clinical evaluation is done by 3rd parties and in this, the contribution of India is only 1%. This indicates the huge scope of clinical research in India with emerging ample opportunities for pharmacy graduates.

The clinical research at present, in India mainly encompasses Bioequivalence/Bioavailability studies for generics and short-term registration trials for registering the new drugs. The evolution of clinical research in India started less than 10 years ago. The potential of clinical research had been identified and now government has taken the initiative by defining the ground rules, releasing Indian GCP guidelines by DCGI and biomedical ethics guidelines by ICMR-a key milestone for clinical research in our country.

This milestone requires 3 Ps for success namely purpose, process and people.

1. *Purpose: It is to have clear vision regarding the clinical research and the mission is to achieve it with proper business plan.*
2. *Processes: The intensive knowledge needs to be generated, recorded and properly handled.*
3. *People: The purpose of the clinical research is " For the people, on the people, done by the people". So it is very important, the people who are involved in the clinical research should be trained professionals.*

Clinical research demands the thorough knowledge of guidelines to meet the requirements of the processes involved. India is a vast ocean of knowledge driven people and we have to traverse a long path to be carved with qualitative input of efforts for proper definition of systems. The quality can be assured if the people involved are professionals and who are thoroughly trained to meet the challenges. Clinical research involves lots of documentation from regulatory point of view and the data management. The documentation will be proper only if the information to be handled in it is well know by the person and is aware of the technical aspects involved in clinical research. As a part of curriculum in India, Pharmacy graduates are taught all the aspects related to drug, right from the pharmacology to the production. Hiring and training these professionals would enhance the quality of work and simultaneous training will increase the quality of output. Hence induction of pharmacy professionals will certainly lead to quick achievement of the purpose of clinical research in India-" To make clinical research in India, a GCP compliant one".

Scientific Oral Presentations

Orals	Scientific Session	P. No.
A_1 to A_{72}	Pharmaceutical Technology	1
B_1 to B_{36}	Medicinal Chemistry	29
C_1 to C_{36}	Pharmacognosy and Phytochemistry	44
D_1 to D_{36}	Indigenous Drugs, Herbal and its Formulations	57
E_1 to E_{36}	Pharmacology and Toxicology	70
F_1 to F_{18}	Biopharmaceutics, Pharmacokinetics & Drug Metabolism	84
G_1 to G_{36}	Pharmaceutical Analysis and Quality Assurance	91
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I_1 to I_{19}	Hospital and Clinical Pharmacy	112
J_1 to J_{18}	Pharmaceutical Education	120
K_1 to K_{18}	Professional Pharmacy, GMP & TQM	127
L_1 to L_{15}	Regulatory Affairs in Pharmacy	135

A1 Biodistribution and tumour uptake studies of ^{99m}Tc labelled cytarabine loaded long circulating liposomes

N. Subramanian[1*], N. Arulsudar[1], P. Mishra[2], R. K. Sharma[2] and R. S. R. Murthy[1]

[1]New Drug Delivery Systems Laboratory, Pharmacy Department, Donor's Plaza, M.S.University of Baroda, Vadodara.

[2]Division of Bio cybernetics and Radiopharmaceuticals, Institute of Nuclear Medicine and Allied Sciences, Brig. S.K. Mazumdar Road, Delhi.

The aim of the present study is to investigate the effect of polyethylene glycol coated liposomes containing cytarabine on the blood circulation time and also on the tumour targeting in Ehrlich ascites tumour bearing mice. The conventional and long circulating liposomes containing cytarabine were prepared using egg phosphatidyl choline and cholesterol by lipid film hydration method with the entrapment efficiency of 83.5 and 82.2 % respectively. In case of long circulating liposomes, methoxy polyethylene glycol 5000 -Phosphatidylethanolamine (mPEG5000-PE) was used along with the lipids to provide surface hydrophilicity to the liposomes. The prepared liposomes were passed repeatedly through 0.2µm track-etch polycarbonate filters. The characterization of the prepared liposomes was carried out for its particle size which showed that the average mean particle size of the liposomes were around 200nm. Conventional and long circulating liposomes containing cytarabine were labelled directly with ^{99m}Tc after reduction using stannous chloride at pH 7. The ^{99m}Tc-drug / liposome complexes were intravenously injected through the tail vein of Balb/c mice bearing Ehrlich Ascites tumour in the left thigh region. The biodistribution studies carried out in the mice, showed prolonged circulation in blood and significant increase in the accumulation in tumour for the long circulating liposomes compared to the conventional liposomes and the free drug. The gamma scintigraphic study also supports the biodistribution results. The present study suggest that long circulating liposomes could serve as an alternative mode of delivery for cytarabine with high blood circulation and tumour targeting of the liposome formulations containing cytarabine in the tumour bearing mice.

A2 Controlled release of nimesulide from combined eudragit RS 100 and hydroxy propyl methyl cellulose matrix tablets

K.E.V. Nagoji*, S. Srinivasa Rao, S. Vijaya Srinivas and M.E.B. Rao.

Pharmaceutics Division, Roland Institute of Pharmaceutical Sciences, Berhampur (Gm) 760 010, Orissa.

The matrix tablets of nimesulide were prepared by using a combination of hydrophobic polymer (eudragit RS 100) and hydrophilic polymer (hydroxy propyl methyl cellulose) as matrix material. The matrix material was used in three different concentrations, 5%, 10% and 20%, w/w. In the case of matrix tablets containing 5% w/w of combined matrix material. Eudragit RS 100 and HPMC were used in the ratios 1:2, 1:3 and 1:4 whereas, in the case of matrix tablets containing 10% w/w of combined matrix material, eudragit RS 100 and HPMC were used in the ratios 1:2%, 1:4% and 1:6 and in the case of matrix tablets containing 20% w/w combined matrix material eudragit RS 100 and Hpmc were used in the ratios 1:3, 1:6 and 1:9. Matrix tablets containing only eudragit RS 100 were also prepared. The drug release from the matrix tablets containing only eudragit RS 100 as matrix material was slow and follows zero order kinetics and diffusion mechanism. Whereas, the drug release from the matrix tablets containing the combinations of eudragit RS 100 and HPMC, the drug release depended on the hydrophilic polymer was increased. The rate of drug release was also increased. The drug release from these tablets deviated from zero order to first order kinetics and the mechanism of drug release deviated from diffusion to other than diffusion as the hydrophilic matrix material concentration. As the concentration of hydrophilic polymer was increased, the rate of drug release was also increased. The drug release from these tablets deviated from diffusion to other than diffusion as the hydrophilic matrix material concentration increased. The matrix tablets formulation containing 5% w/w of the combined eudragit RS 100 and HPMC in the ratio 1:3 showed the drug released pattern very close to the theoretical drug release needed for controlled release dosage form of nimesulide. This formulation remained stable during the 12 months period of the stability study. The pharmacokinetic parameters calculated after the oral administration of the proposed controlled release formulation of nimesulide to six human volunteers revealed that this formulation fulfilled all the characteristics required by the oral controlled release dosage forms of nimesulide.

A3 Improved dissolution of Silymarin via solid dispersion

N.H. Indurwade, P.S.Kawtikwar, Bhavana R.Patel, V.V. Redasani*

Department of Industrial Pharmacy, S.N.Institute of pharmacy, Pusad 445 204

The objective of this study was to improve the dissolution rate of a water insoluble drug, Silymarin, by solid dispersion systems with mannitol and PEG'S (PEG 4000 and PEG 6000). Thin layer chromatography and UV scanning were performed to evaluate any compatibility problem. The dissolution rate of Silymarin was markedly increased in solid dispersion of mannitol and PEG too. Solubility studies revealed a marked increase in the solubility of Silymarin with an increase in mannitol concentration. The result from TLC and UV scanning indicated that there was no interaction between drug and carrier. The potential Silymarin degradation peaks were not detected in any UV scanning taken over the course of 72h, studies, indicating that dispersions were quite stable. The greatest enhancement in Silymarin dissolution was achieved from Silymarin: Mannitol (1:5) dispersion.

A4 Controlled release and sustained hypoglycemic effect of glipizide from mucoadhesive microcapsules

K.P.R.Chowdary* and Y.Srinivasa Rao

Department of Pharmaceutical Sciences, Andhra University, Visakhapatnam 530 003.

Mucoadhesion has been a topic of current interest in the design of drug delivery systems to prolong the residence time of the dosage form at the site of absorption and to enhance the bioavailability of drugs. The objective of the study is to develop, characterize and evaluate mucoadhesive microcapsules of glipizide for controlled release and *in vivo* hypoglycemic effect.

Microcapsules containing glipizide were prepared employing sodium alginate in combination with four mucoadhesive polymers - sodium CMC, methyl cellulose, Carbopol and HPMC - as coat materials. An orifice-ionic gelation process was employed to prepare the microcapsules. The microcapsules were evaluated for drug content and microencapsulation efficiency, SEM, *In vitro* drug release and mucoadhesion and *in vivo* hypoglycemic effect. *In vivo* evaluation of the microcapsules was performed in normal healthy rabbits by measuring serum glucose levels following their oral administration as per cross-over RBD (n=4). Serum glucose concentrations were determined by oxidase-peroxidase method.

The microcapsules were found to be discrete, spherical, free-flowing and of the monolithic matrix type. The microcapsules exhibited good mucoadhesive properties. Glipizide release from these mucoadhesive microcapsules was slow and extended over longer periods of time and depended on composition of the coat. Drug release was diffusion controlled and followed zero order kinetics. In the *in-vivo* evaluation, alginate-carbopol microcapsules could sustain the hypoglycemic effect of glipizide over a 14-hour period. These microcapsules are, thus, suitable for oral controlled release of glipizide.

A5 Revolution in technology: smart sensing electronic tongue to analyze mouth dissolving tablet

Chandrashekar.N.S.*[1], D.Ravikumar[2], P.Parimala [2], P.K.Kulkarni [1]

1. J.S.S.College of Pharmacy S.S.Nagar Mysore 570015
2. Karnataka Antibiotics and Pharmaceuticals Ltd, Bangalore 560058 Formulation Research and Development

The electronic tongue (E-tongue) system represents a new revolutionary smart sensing technique in the field of rapid analysis for formulation development of oral dosage form. From laboratory to production in the pharmaceutical industry the use of sensory panelists is very difficult and problematic in the industry .This is due to potential toxicity of the drugs and subject to several other aspects like recurring taste panelists , motivation and maintenance of the taste panelists especially when working with unpleasant product and non-FDA approved molecules. In this report mouth dissolving tablets (MDT) are formulated of NSAID'S. These tablets are recommended for patient with difficulty in swallowing and dysphiga like in the case of children and old people. Disintegration time in mouth, flavor concentration, bitter measurement, bittermasking , and organoleptic properties.E-tongue is scientific apparatus, which mimic the disintegration process that takes place in the mouth, which contains specific software with two variable flow rate pumps (5ml/min-400ml/min) with artificial saliva. The system gives results in few minutes both qualitative and quantitative. The tablet is placed manually in the apparatus and the time taken for the disintegration is calculated by software. The studies are conducted in the triplicate (3times) average disintegration time is calculated (15-18 seconds) and a calibration graph is constructed for different concentrations (minimum 5 in number). This helps in the analysis of unknown sample concentration. Bitter masking analysis carried out with placebo which is formulated with different concentration of the bittermasking agent and correct

concentration is known from graph plotted. Bitterness measurement is a scale from1-20 (1 is bitter taste, 20 is no bitter) is drawn depending on the intensity and subjectivity of the bitterness a scale is constructed with the different intensity of the bitterness. The instrument is calibrated with different concentration and unknown sample concentration of the bitterness is known. In the bitterness matching the taste of the placebo is matched at various concentration to get optimized target. Targeted concentration, the time required for entire analysis is 3 minutes, and the results are reproducible hence the entire methodology is very simple and is carried out at the room temperature with no other sample preparation requirement. The E- tongue technology offers promise in providing the evaluation development as a quality control tool wide range of formulations can be screened in minutes with electronic tongue compared to number of samples screened with human sensory panel in the same amount of time. Like human being the instrument has to learn the different reference taste to analyze and to identify the unknown product for the first time.

A_6 Formulation and *in vitro* immunosuppressive evaluation of cyclosporine loaded liposomes

N. Arulsudar[a]*, N.Subramanian[a], B.S. Dwarakanath[b], R. K. Sharma[b] and R.S.R. Murthy[a]

a. New Drug Delivery Systems Laboratory, Pharmacy Department, Faculty of Technology and Engineering, M.S.University of Baroda, Kalabhavan, Vadodara-390001, India

b. Division of Biocybernetics & Radiopharmaceuticals, Institute of Nuclear Medicine and Allied Sciences, Brig. S.K. Mazumdar Marg, Delhi, India

The study focuses on the preparation and characterization of cyclosporine (CsA) loaded various charged (positive, negative and neutral) liposomes as stable lyophilised powder with high entrapment efficiency. Further, we investigated the *in vitro* immunosuppressive effects of liposomal CsA formulations with that of free CsA in mouse splenocytes. The liposomes were characterized for encapsulation efficiency, shape and particle size. The average particle size of the formulated liposomal formulations was less than 200nm and was spherical in shape with encapsulation efficiency of more than 90%. Alterations in the CD4 and CD8 positive cells as well as induction of apoptosis in mouse splenocytes *in vitro* were studied by multiparameter flow-cytometry to evaluate the efficacy of the formulations. Significant differences could not be observed in the effects of free CsA and the liposomal preparation on the CD4 and CD8 in vitro. Hence the findings demonstrate the efficacy of the three liposomal formulations for the induction of apoptosis in mouse splenocytes as compared to the free cyclosporine at 24h at a concentration of 1.0 μM and 10 μM. Flow cytometric analysis using monoclonal antibodies specific to particular splenocyte subsets showed that cyclosporine and its liposomes induce a decrease in the % of CD4+ and CD8+ cells at 1.0 μM. In vitro effects on the splenocytes indicates that positive CsA liposomes at 1.0 μM, induces a marginally higher level of cell death than free CsA, while the effects of negative and neutral CsA liposomes are similar to free CsA, suggesting the improvement in the efficiency of liposome mediated drug delivery containing CsA.

A_7 *In-vitro* study of salbutamol liposomal nebulizing solutions and comparative study of nebulizing devices

Anubha Khale*, Amrita Bajaj, Rajkumari A.

C.U.Shah College of Pharmacy, S.N.D.T. Univ., Mumbai-49.

Salbutamol Sulphate, α-2 agonist was encapsulated in liposomes which were formulated as nebulizing solutions for controlled pulmonary delivery. Liposomal carrier systems were used for altering the pharmacokinetics of the drug to prolong its residence time within the airways, decreasing the distribution to other sites.

A prerequisite for therapeutic efficacy is the ability of the aerosolised drug to reach the peripheral airways. The deposition of the inhaled aerosol is governed by the inertial impaction, gravitational sedimentation and Brownian diffusion of the aerosol particles. The fate of aerosolised medication is determined by the aerodynamic diameter of the particles or droplets.

Biopharmaceutical assessment of the liposomal nebulizing solution, *in-vitro* was done by measuring the drug mass distribution among the various aerodynamic size ranges of the aerosols. Two stage deposition in Twin Impinger, a specifically designed apparatus which gives the particle size deposition in the range of 0.3 μm to 10 μm was used for the purpose.

Though, nebulization is the effective way to deliver liposomes to the respiratory tract, stability of liposomal vesicles during nebulization is an important aspect. The nebulizer design is an integral part of the liposome drug delivery system by inhalation route. As the change in the type of nebulizer can alter the release characteristics of the vesicles, it becomes necessary to specifically define the type of nebulizer to be used for delivery of liposomal products.

The delivery of Salbutamol Nebulizing solutions was studied by a Jet Nebulizer of Clenny and an Ultrasonic Nebulizer of Citizen. The two nebulizers were compared on the basis of following tests –

1. Inhaled aerosol mass and spray rate.
2. Particle size distribution analysis and net respirable fraction.
3. Particle size after nebulization by Laser Diffraction method.
4. Vesicle integrity after nebulization by Transmission Electron Microscopy.

The above tests confirmed the deposition of the liposomal nebulizing solution of Salbutamol to the peripheral airways and vesicle integrity to exert sustained release of the drug.

A_8 Formulation and *in-vitro* evaluation of etoposide encapsulated solid lipid nanoparticles

Patlolla R. Reddy*, Kopparam Manjunath, Prabhakar R.Veerareddy, V.Venkateswarlu**

UCPSC, Kakatiya University, Warangal A.P. 506 009

The use of novel drug delivery systems in cancer therapy is a promising approach. Etoposide is a derivative of podophyllotoxin that has shown promising anticancer activity. Solid lipid nanoparticle (SLN) delivery systems of etoposide have been developed by hot homogenization of melted lipids and aqueous phase followed by ultrasonication. Particle size and charge measurements were made with Malvern Zetasizer. Entrapment efficiency of etoposide was determined by ultracentrifugation method. *In vitro* release studies were performed using modified Franz diffusion cell.

Stable SLN formulations of etoposide having mean size 258.5 nm and zetapotential of -32.4 mV were developed. More than 90 % etoposide was entrapped in SLN. *In vitro* release pattern of drug was analyzed and found to follow first order better than Higuchi and Weibull equations.

A_9 Preparation, characterization and tissue distribution studies of zidovudine nanoparticles

Praveen. S, Shobha Rani R.H* and Kshama Devi

Al-Ameen College of Pharmacy, Hosur Road Bangalore 560 027

A very important challenge today, is the targeting to HIV infected cells. It is now well established that macrophages of the body play an important role in the immunopathogenesis of HIV infection by acting as reservoir for the virus. Nanoparticles (NP) present an interesting system for the transport of Zidovudine, which otherwise has poor selectivity to macrophages and manifests toxicity. The present study aims at investigating the feasibility of employing poly-lactide-co-glycolide (PLGA) NP as colloidal drug carriers for Zidovudine. The NP were prepared by a modified Solvent Displacement method. Optimization of the method of preparation was carried out employing central composite design to determine the variables that leads to the best possible drug incorporation. The NP were then characterized for their morphology, size distribution, drug incorporation and *in-vivo* tissue distribution. Stability studies as per ICH guidelines were carried out to assess the NP stability and shelf life. The optimization studies revealed that the PLGA concentration had a prominent effect on the response ($p<0.01$). Morphology studies showed spherical, discrete particles in the nano range and NP size had a normal distribution with an average particle diameter of 450 nm. About 88% of the drug was incorporated in the NP of which 51 % was in the matrix and 37% had adsorbed on the surface. *In-vivo* tissue distribution studies showed that the NP of Zidovudine targeted the RES organs to a large extent when compared to Zidovudine conventional formulations. These studies prove that NP of Zidovudine is a promising 'Targeted Drug Delivery' approach, which results in, increased selectivity of the drug, probable reduction in toxicity and thus improve HIV therapy.

A_{10} Studies on formulation of multiple nanoemulsions of insulin

Vaishali H. Nikam* and K.K.Singh

C.U.Shah College of Pharmacy, S.N.D.T. Women's University, Santacruz (W), Mumbai- 49

Multiple emulsions are more complex system, termed "emulsions of emulsions"; the droplet of dispersed phase themselves contain even smaller dispersed droplets. Many lipid carrier systems have ability to promote oral absorption of conventional drugs, peptides and proteins. The covalent attachment of peptides to lipids has been proposed as a means for absorption enhancement e.g. covalent complexes between insulin and cationic triglyceryl carriers show a hypoglycemic effect when given orally. Besides limitations of subcutaneous administration of insulin have prompted the exploration of non-invasive routes and novel drug delivery systems (NDDS) for insulin administration. Multiple emulsions are cheaper alternatives, which are easier to manufacture, store and scale-up. They elicit their response more reliably.

The emulsions were prepared by a two-step emulsification process using a homogenizer. The formulations were evaluated for different parameters e.g. pH, particle size (Malvern Mastersizer S ver.2.19.), drug content, centrifugation studies, Transmission electron microscopy, *in vitro* drug release and stability studies.

The multiple emulsions with particle size 150nm –540nm has been successfully prepared. The pH of formulation was in the range of 6.2- 7.4.

No creaming, cracking and separation of emulsion was observed on centrifugation at 20000rpm for one hour. On freezethaw cycling the emulsions were found to be stable. The stability studies indicated that the developed nanoemulsions were stable for four months when stored at 2-8°C.

A_{11} Proniosomal drug delivery system of ethinylestradiol for hormone repalcement therapy

Suni Kumar Prajapati[1]* and G. P. Agrawal[2]

1. Institute of Pharmacy, Bundelkhand University, Jhansi (U.P)
2. Department of Pharmaceutical Sciences, Dr. Harisingh Gaur University, Sagar (M.P.)

The significant failure rates of Ethinylestradiol related to users compliance and associated side effects are major limitations in their successful use. The present investigation was taken to prepare and evaluate proniosomal gel as rate controlling vesicles/ gel for transdermal use and to study the effect of different concentrations of spans on the release rate. Proniosomal gel containing Ethinylestradiol & Levonorgestrel were prepared using different non-ionic surfactants like span 20, 40, 60 & 80 in the ratio 20:40(11), 20:40(2:1) 20:40(3:1), 20:40(4:1), spans mixtures 20:60, 20:80, 40:60, 80:60 & 20:40(3:1) with Brij, DCP, EL, SL,CHL by Coaservation Phase Separation method. *In vitro* release rate studies were performed using cellophane membrane for different Proniosomal formulation in triplicate, transdermal flux, release rate & slope value were calculated from data. The release rate were in following order for mixture of mixture of Spans SKR4, SKR3, SKR3,SKR1 Selected formulation SKR3 shows maximum transdermal flux with isopropyl alcohol. The release rate were in following order for different alcohol's i.e. SKI, SKB,SKP,SKAA. In combination mixture of span the release rate was found in order 20:80>80:40>80:60> 20:60. All the formulation containing spans released significantly less drug Ethinylestradiol than phospholipids formulation Brij (SKM1)>SL(SKM4)> DCP>(SKM3)>EL(SKM2) >CHL(SKM5).

On the basis of these release rate studies & stability studies formulation SKR3 containing Ethnylestradiol were optimized for *In-vivo* study of Ethinylestradiol proniosomal gel in immature albino rats of 23-25 days old was performed. Only two formulations SKR3 and SKM4 were selected for characterization of niosomes formed from Proniosomes after hydration. The transdermal flux of proniosomal formulations in different ratio was seen in the following order SKS4 >SKS3>SKS2>SKS1. In conclusion the proniosomal gel system shows great potential for preferred delivery of Ethinylestradiol drug for their use in Hormone replacement therapy.

A_{12} Development and application of Rocket Electrophoresis technique in preformulation studies of tetanus vaccine formulation

Vijay J. Ahire * and Krutika K. Sawant

Pharmacy Department the M. S. University of Baroda, Vadodara 390 001

Antigens can be quantified by electrophoresing them into antibody containing gel in the technique termed Rocket Electrophoresis (RE). The pH of the gel is chosen so that antibodies are immobile and the antigen is negatively charged. Precipitin rockets form, the height of the rocket is proportional to antigen concentration. The technique relies on the difference in charges of the antigen and antibodies at the selected pH. The tetanus or any other toxoid can be stadardized using Antitoxin Standard by RE. The appropriate equation can be obtained between the antigen and the rocket height, and can be used qualitatively and quantitatively. TT was electrophoresed using 1% Agarose gel in Tris-Glyeine buffer (pH 8.6) containing Tetanus Immunoglobulin GI IU/ml at 4-8°C for 18 hrs. The heights of the rocket shaped precipitate were measured after staining with Coomasie Blue R. This technique was applied as a preformulation tool for the evaluation of the stability of TT in presence of various additives to be used in the vaccine formulation. The concentration of TT in marketed Tetanus Vaccine (Adsorbed) was estimated, after elution using trisodium citrate by RE conclusion drawn are the flocculation test can be replaced by RE. RE results are less prone to operator's bias as compared to flocculation test and can be documented by taking photograph and / or scanned by densitometer. RE can be easily standardized for the required antigen concentration by changing antitoxin concentration. It can be used as a very effective tool for the preformulation studies of antigens.

A_{13} Controlled release intra uterine device (IUD) with levonorgestrel

Jayakumar M*, Ganesan M, Senthil Rajan D, Uttam Kumar Mandal, Pal TK, Shampa Biswas[1], Pal AK[1] and Kabir SN[1].

Department of Pharmaceutical Technology, Jadavpur University, Kolkata - 32.

1. Indian Institute of Chemical Biology, Kolkata - 32.

Population explosion is a major obstacle for the development of any country. Commonly available contraceptive methods like condom, pills were often forgotten most of the time when sexually aroused! More over in India, contraception has mainly remained

the responsibility of women. Hence its obvious that convenient long-acting contraceptive methods are becoming more & more appealing. Intra-uterine contraception is entering a new phase with the development of intra uterine systems (IUS's) that will deliver potent progestins directly into the uterus, without affecting the systemic hormonal balance.

In the present work two biocompatible polymers, Ethylene vinyl acetate (EVA) and poly vinyl acetate (PVA) were used for preparation of IUD. Different proportions of EVA & PVA mixtures (1:1, 1:2, 1:3, 1:4 & 1:5) were dissolved in dichloro methane containing calculated quantity of Levonorgestrel (LNG). The polymer solution was allowed to evaporate and the drug containing matrix was hot compressed to give cylindrical mould (size: 2mm diameter & 20mm length). The IUD was characterized for *in-vitro* drug release as per USP XXII guidelines and evaluated for their in-vivo anti fertility efficacy using laboratory animals. The results revealed that mixture of EVA & PVA in the ratio of 1:4 showed optimal results like flexibility, strength & controlled drug release pattern. The release profile showed higher correlation coefficient for Higuchi plot.

No cyclic change (or) ovulation rate was observed in animals implanted with the IUD. The device was found to prevent fertilization rather than implantation. The present study can be extended for further improvement of the IUD, which will be a real substitute for Cu-T.

A_{14} Studies on the development of oral targeted delivery systems for albendazole

Y.S.R. Krishnaiah, P. Bhaskar and S.S. Shyale*#

Department of Pharmaceutical Sciences, Andhra University, Visakhapatnam 530 003

V.L.College of Pharmacy, Raichur 584 103

The aim of the present investigation was to develop oral colon-targeted drug delivery systems for albendazole using guar gum as a carrier. Albendazole is poorly absorbed throughout the GIT. Hence, it was planned to improve its availability by forming complexes with beta-cyclodextrin. Matrix tablets of albendazole-beta-cyclodextrin complexes in the ratio of 1:0.25 (equivalent to albendazole 200mg) were prepared by wet granulation method using starch paste as a binder. Guar gum was included in the formulations in various proportions 20% (ABC-20), 30% (ABC-30), and 40% (ABC-40). The matrix tablets were evaluated for hardness and drug content, and were subjected to *in vitro* drug release studies. The amount of albendazole released from the matrix tablets at different time intervals was estimated by HPLC method. Guar gum-based beta-cyclodextrin matrix tablets released 4 to 15% of albendazole in the physiological environment of stomach and small intestine depending on the proportion of guar gum used in the formulation. When the dissolution study was continued in simulated colonic fluids (rat caecal content medium) the matrix tablets containing 20% of guar gum released another 70% of albendazole after degradation into 2-3 pieces at the end of 24 h of the study. The matrix tablets containing 30% of guar gum also released about 54% of albendazole in simulated colonic fluids at the end of 24 h of the study indicating the susceptibility of the guar gum formulations to the rat caecal contents. The results of the study show that matrix tablets containing 30% of guar gum are most likely to provide targeting of albendazole for local action in the colon owing to its controlled release of the drug in the first 5 hours. The *in vivo* evaluation of guar gum-based colon-targeted beta-cyclodextrin matrix tablets was carried out in healthy human volunteers to find in vivo performance of colon-targeted matrix tablets of albendazole. The results of the study indicated that the guar gum-based colon-targeted formulation was not released in stomach and small intestine, but delivered to the colon resulting in a slow absorption of the drug and making the drug available for local action in the colon.

A_{15} Application of *Hibiscus rosa-sinensis* gum as a suspending agent in the formulation of rofecoxib suspensions

M. Satish Kumar

H.No. 11-29-186/1, 2nd Bank Colony, Deshaipet Road, Warangal 506 002. A.P.

Rofecoxib, chemically 4-[4-(methyl sulfonyl) phenyl]-3-phenyl-2 (5H)-furanone is a new non-steroidal anti-inflammatory drug (NSAID). Cyclooxygenase-2 (COX-2) inhibitors were brought to the market as a safer alternative to traditional NSAIDs because of reduced incidence of side effects. Rofecoxib is a selective COX-2 inhibitor, comparatively exhibits lower incidence of symptomatic gastroduodenal ulcer complications than other NSAIDs. It is used in the treatment of osteoarthritis, acute pain and rheumatoid arthritis. Rofecoxib is also used in the treatment of post-operative dental pain and primary dysmenorrhoea. Many of the more recently developed drugs are poorly water soluble in nature including rofecoxib. Thus solutions of these drugs, containing an appropriate dosage, would be of an unacceptably large volume. Suspensions allow the development of a liquid dosage form containing an appropriate quantity of drug in a reasonably small volume. Formulation of an effective and pharmaceutically elegant suspension in usually much harder to achieve than that of a tablet or capsule of the same drug. No work was reported on the formulation of rofecoxib suspensions. In the present work an attempt has been made to study the effects of various suspending agents including *Hibiscus rosa-sinensis (Hibiscus)* gum on the stability and dissolution rate of rofecoxib suspensions.

In recent years, plant hydrocolloids have evoked tremendous interest due to their diverse applications in pharmacy. Modified form of gum karaya was evaluated as a disintegrant. Abelmoschus esculentus[11] gum was studied in the formulation of sustained release tablet dosage forms. Oral colon targeted drug delivery systems were developed by using guar gum as a carrier. Gums find wide pharmaceutical application as thickening agents and protective colloids to stabilize suspensions and emulsions. In the present work gum extracted from the leaves of *Hibiscus rosa-sinensis* was also tried as a suspending agent in addition to sodium carboxymethylcellulose (sod.CMC), sodium alginate (sod.alg) and polyvinyl pyrrolidone (PVP). *Hibscus rosa-sinensis* is an evergreen, woody, glabrous, showy shrub of the *Malvaceae* family, found in entire India. Traditionally, a decoction of leaves is taken orally as an aperient, laxative, anodyne and to expel the placenta after child birth; externally in combination with juice of *Veronia cineria* it is used as an emollient[14].

A16 History repeats: after 50 years a new trend, chewing gum as a drug delivery

P. Parimala*, D. Ravikumar, Chandrashekar N.S, P.K. Kulkarni

1. Karnataka Antibiotics and Pharmaceuticals Ltd Bangalore 560 058
2. Formulation Research and Development, J.S.S College of Pharmacy, S.S.Nagar, Mysore 570 015

Interestingly,chewing gum is becoming an alternative drug delivery system when considering oral administration of drug substances, because of its advantages over conventional administration. Present study to formulate and evaluate the sugar free chewing gum, and to determine the *in vitro* release, stability studies of the formulated preparations chewing gum, which will be useful for the treatment of Caries and Xerostomia, the chewing gum are formulated by Gum base, with glidants, fillers, flavors preprations of the chewing are prepared by direct compression on a flat punch of 10mm and invitro dissolution studies were carried out using dissolution special apparatus which mimic the human chewing action with variables include chewing frequency, distance between and twisting action of jaws, as well as chewing time,volume and temperature of saliva, which show the better *in vitro / in vivo* correlation, xylitol was used as model drug with different intensity of chewing frequency with difference in distance between the surfaces, stability studies as ICH guidelines confirms that no change in shape, color ,texture, appearance unchanged.

Chewing gum is no longer seen simply as confectionery. A bright future for preparation with long history.

A17 Evaluation of natural gum (gum copal) as a sustained release matrix forming material

S. S. Tripathi*, D. M. Morkhade,U. V. Barabde S.V. Fulzele, P. M., Satturwar, and S. B. Joshi.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur 440 033.

Significant emphasis is directed towards evaluation of natural polymers for various pharmaceutical and biomedical applications. These materials are expected to be biocompatible, cost effective and eco-friendly apart from achieving specific drug delivery objective and therefore they are recently finding an ever-interesting range of application in pharmaceutical dosage form designs.

Copal gum is a natural resin from *Bursera bipinnata*. Evidences has been offered by literature that it is used as dietary food, meat preservative, remedy for stomach pain, fright, dizziness, loose teeth and dysentry. Being of natural origin and above applicability it can promise better biocompatibility.

For sustained release device formulation, the least complicated approach is to fabricate the matrix tablets. Therefore the present research was undertaken to investigate a novel gum (copal) as a sustained release matrix former using Diclofenac Sodium as a model drug. Various sustained release (SR) formulations of copal gum were prepared by wet granulation technique using dicalcium phosphate and microcrystalline cellulose as diluents and they were evaluated for weight uniformity, hardness, friability, drug content and *in vitro* drug release. To study the exact release mechanism, release data is analyzed according to zero order first order and Higuchi equation. Release data was found to follow Higuchi square root model. 20% w/w gum copal in formulation significantly sustained the drug release upto 10 hours. Present findings thus promise the utility of gum copal as a new sustained release matrix former.

A18 Membrane moderated TTS of flurbiprofen in HPMC matrix with EVA

S.S. Shyale, S.M. Shantakumar, T.S.S. Prasanna D. Manjula, O. Palakshi Gouda*

Dept. of Pharmaceutics, V.L. College of Pharmacy, Raichur 584 103, Karnataka

In this investigation, the drug release kinetics of Flurbiprofen as a model drug, in HPMC monolithic reservoir matrix through EVA-2825 as rate controlling membrane with or without Eucalyptus oil (1% w/w) was studied. Various physical characteristics like solubility, partition coefficient, %WVT, thickness and

SEM were studied. *In vitro* release studies were conducted in Keshary-Chien diffusion cells across excised hairless rat skin. Hypersensitivity reactions test was carried out on guinea pigs and analgesic and anti-inflammatory activity on mice and rats respectively were conducted.

The thickness of the films remained uniform and consistent, SEM photomicrographs revealed smooth surface with uniform and regular pores. In vitro studies indicate perfect zero order release of drug through both films without or with eucalyptus oil, (n = 1). Further, the eucalyptus oil increases the flux of the drug. No allergic manifestations were observed on guinea pig skin. *In vivo* activity on mice and rats showed significant analgesic and anti- inflammatory activity ($p < 0.05$).

A_{19} Formulation and evaluation of *in-situ* gel implants of glibenclamide

S. Mutalik, S.Agarwal, G. Subramanian, R. Karki, N. Udupa

College of Pharmaceutical Sciences, Manipal 576 119, Karnataka

Glibenclamide, an important drug for non-insulin dependent diabetes mellitus, has been associated with severe hypoglycemia and gastric disturbances after oral therapy. Since this is usually intended to be taken for a long period, patient compliance is also very important. Novel drug delivery systems like implants offer many advantages to overcome these problems. In the present work attempt has been made to formulate and evaluate *in situ* gel implants of glibenclamide using poly (lactide-co-glycolic) acid (PLGA).

The possible interaction between glibenclamide and PLGA was studied by Infra-red spectroscopy, Differential scanning calorimetry and High performance thin layer chromatographic analysis. The implants were prepared with different drug and polymer ratios (1:5, 1:7.5 and 1:10). The *in vitro* drug release experiments were conducted by vial method. The morphology of the in situ gel implants before and after in vitro skin release studies was analyzed by scanning electron microscopy (SEM). Hypoglycemic activity of implants was carried out in normal and streptozotocin induced diabetic mice. Various biochemical parameters like serum lipid profile (high-density lipoprotein (HDL), triglycerides and total cholesterol), alanine transaminase (ALT), aspertate transaminase (AST), urea and creatinine levels and hepatic protein and glycogen levels were analysed in diabetic mice after 30 days treatment. Liver, pancreas and stomach were subjected to histopathological examination. Skin toxicity study was performed by visual observation and histopathological evaluation.

There was no interaction between drug and PLGA as there were no changes in the principal IR peaks, melting point and R_f values of drug in the presence of PLGA. The percentage of drug release was decreased as the proportion of polymer was increased. The SEM studies revealed the formation of big pores after the drug release studies. Implant with drug and polymer ratio, 1:10 was selected for *in vivo* studies. The implants and oral glibenclamide administration produced similar level of hypoglycemic effect in both normal and diabetic mice upto 30 days. The biochemical parameters and tissue toxicity in diabetic untreated mice were significantly reversed by glibenclamide implants. These favourable effects were more pronounced with implants, which could be due to day-to-day glycemic control. Negligible skin toxicity was observed at the site of implantation.

The present study showed that glibenclamide implants exhibited better control of hyperglycemia besides more effectively reversing the complications associated with diabetes mellitus.

A_{20} Study of ghee as a vehicle for cream

A.V. Asati, D.R. Mundhada and P.G. Yeole*

Institute of Pharmaceutical Education and Research, Wardha 442 001 (M.S.)

Ghee by virtue of its lipophilicity has been used as a vehicle for semisolid preparation since ancient age. Ghee bears several medicinal claims and many of its combination with herb were reported, for its cooling and emollient effect as stomachic, nutrient tonic and more importantly it promotes wound healing. Chemically Ghee contains saturated and unsaturated fatty acids include olic, linolic, palmitic and stearic acids. Thus by keeping in a view above properties of Ghee, in present investigation it was used as vehicle for preparation of cream and Clotrimazole as model drug.

By using different composition of Ghee, o/w types of various aqueous creams were formulated with the help of adjuvant. Finally o/w cream containing 30% w/v Ghee, 1% Clotrimazole were selected due to its better texture, spreadability. These formulations were evaluated for various parameter like drug content, viscosity, spreadability, pH, consistency, homogeneity, skin irritation. The stability study were performed up to 3 month at different temperatures at 75% RH. Also evaluated for *in-vitro* release of Clotrimazole by using modified Keshary Chien type diffusion cell. The antimicrobial activity of the developed cream was also determined on strain like *Staphylococcus aureus, Candida albicans, Tricophyton rubrum, Malassezia furfur* by agar cup plate method. The same was compared with two marketed aqueous cream (M1, M2) containing 1%w/w Clotrimazole.

The prepared cream formulation shows Drug content within the standard limit, good spreadability,

homogeneity, smooth texture, neutral pH, no skin irritation and proper consistency. The results for *in-vitro* release followed zero order kinetic. The cream was stable upto 3 month at 45°C at 75% RH. The antimicrobial activity of cream containing ghee comparatively more than marketed preparation and gave better result. Due to the promising result of Ghee, it can be concluded that the Ghee may be used as a semisolid base but further it also requires extensive stability studies.

A_{21} Studies on fabrication and evaluation of fenoverine - pectin with HPMC & based hydrophilic matrix tablets for controlled release

K. Purushotham Rao, B. Prabhu Shankar* R. Ashok Kumar, Md. Azeemeddin Khan & B.S. Nath

H.K.E. College of Pharmacy, Gulbarga (Karanataka) J. N. T. U. Hyderabad (A.P)

Fenoverine, a choicest drug as gastro intestinal calcium modulator, useful in the treatment of Irritable Bowel Syndrome (IBS) commercially available in 100 mg capsule dosage form taken thrice daily. In the present work Fenoverine is formulated as a matrix tablets using Pectin alone and combination of HPMC and HEC the hydrophilic polymers for controlled release. The *in vitro* drug release was studied using USP Dissolution Apparatus in varied pH conditions of 2 hours in pH 1.2, 4 hours in pH 4.5 and subsequent 2 hours in pH 7.4 phosphate buffer. The data showed that at time intervals of 2,6 and 8 hours 39%, 24.22%, 12.8% and 100% 78%, 59.79% and 100%,100%, 88.8% of the drug was found to be released at respective time intervals. The results showed that Pectin HEC system gave slowest release of Fenoverine. When the Fenoverine drug release data was plotted according to the first order rate equation, all the three plots were found to be fairly linear and the drug was found to obey first order rate kinetics. The results of Fenoverine release from these matrix tablets was also found to obey Higuchi's diffusion equation (0=k t½) , and gave rate of diffusion values 60.72, 48.40 and 38.06 mg / hr ½ for the three matrix tablets. The swelling behaviour of these matrix tablets has been confirmed by the N value obtained from Peppa's plots. The values were found to be 0.7, 0.9 and 1.80 for Pectin alone. Pectin with HPMC and Pectin with HEC respectively. As the values are more than 0.5 it can be concluded that these matrixes have shown considerable swelling followed by diffusion. The results conclusively proved that Fenoverine release is by diffusion with considerable swelling of the matrix. Among the three matrix systems, Pectin + HEC system gave promising results to be useful for the control release of Fenoverine for a period of 8 hours.

A_{22} Evaluation of *Sterculia foetida* gum as sustained-release material

Parad Ved, S.S. Poddar

K.M. Kundnani College of Pharmacy, 47, R.G. Thadani Marg, Worli, Mumbai - 18

The design of sustained-release (SR) product is intended to optimize a therapeutic regimen by providing slow continuos delivery of drug over the entire dosing interval whilst also providing greater patient compliance and convenience. Hydrophillic polymers are becoming more popular in formulating oral SR tablets. Synthetic polymers, natural gums and their derivatives are mainly used as hydrophillic polymers. Natural gums often preferred to synthetic materials due to their safety, economy and availability. One such natural gum would be *Sterculia foetida* obtained from dried gummy exudate of stem bark of *Sterculia foetida* of the family *Sterculiacae*. Since no work has been reported supporting its SR application, the objective of this work was to evaluate Sterculia foetida gum in the designing of SR tablets.

The drug, gum powder and lubricant were sifted separately. Then blended thoroughly in a pestle and mortar with drug (90 mg) in different gum levels (10%, 20%, 30% & 40% w/w). After blending the gum and drug, the mixture was granulated with mixture of IPA and purified water (50:50). The dried granules were lubricated with magnesium stearate.

The pre-weighed amount of blends/granules were compressed into tablets using a rotary tablet press equipped with 7 mm, round, flat-faced tooling. A total of 10 tablets were evaluated for weight, thickness and hardness. Mean and standard deviation were calculated.

The dissolution of diltiazem hydrochloride from all the tablet formulations was measured in 900 ml of distilled water, 0.1 N HCl and in Phosphate buffer pH 7.4 at 37 ± 0.5° C, 50 rpm using USP apparatus type 2 (paddle method). Filtered samples were assayed using spectrophotometer at 237 nm.

A_{23} Formulation and evaluation of Xanthan gum based sustained release matrix tablets of diclofenac sodium

U.C. Galgatte, P.D. Nakhat and P.G. Yeole*

Institute of Pharmaceutical Education and Research, Wardha 442 001 (M.S.)

Diclofenac sodium is most widely used NSAID in the treatment of osteoarthritis, rheumatoid arthritis etc. It has short biological half-life, which requires frequent administration. Hence attempt has been made

to increase therapeutic efficacy, reduce frequency of administration and improve patient compliance by developing sustained release (SR) matrix tablets.

SR matrix tablets of diclofenac sodium were developed by using different drug: polymer ratios such as F_1 (1:0.12), F_2 (1:0.16), F_3(1:0.20), F_4 (1:0.24) and F_5 (1:0.28). Xanthan gum was used as matrix former and microcrystalline cellulose as diluent. All the lubricated formulations were compressed using 8mm round flat-faced punches. Compressed tablets were evaluated for uniformity of weight, content of active ingredient, friability, hardness, diameter and thickness, *in vitro* dissolution and swelling index. All the formulations showed compliance with permissible limits. Among different formulations F_1 showed promising sustained release of drug for 12 hours with 89.665% release and its dissolution profile was compared with marketed tablets which showed 87.214% release.

Selected formulation (F_1) was subjected to stability studies for three months at varying degree of temperature and showed stability with respect to release pattern. I.R. Spectra confirmed no interaction between drug and polymer. The dissolution data of F_1 was subjected to kinetic treatment and Peppas and Korsmeyer diffusion model. The kinetic treatment reflected that the release of drug follows zero order as prominent release kinetic (R^2=0.9758). Further Peppas and Korsmeyer equation resulted into value of n=0.9409 which is approaching to one indicating that the drug was released by approaching zero order kinetic. Thus, Xanthan gum can be used as an effective matrix former to extend the release of diclofenac sodium.

A24 A study on the development of dissolution medium for rofecoxib

N. Mathivanan*, G. Chandra Sekhara Rao, M. Satish Kumar, K.E.V. Nagoji and M.E.B. Rao

Pharmaceutics Division, Roland Institute of Pharmaceutical Sciences, Berhampur (Gm) 760 010. Orissa

Evaluation of pharmaceutical dosage forms for *in vitro* drug release and dissolution characteristics is very important for ensuring batch to batch quality control and to opitimize formulations during product development. In the present study, a new dissolution medium was developed based on solubility data of rofecoxib. Aqueous solubility of rofecoxib containing different surfactants was assessed to prepare dissolution medium, which satisfies sink condition for routine testing of rofecoxib formulations.

Purified water, 0.1 N HCL, Phosphate buffer (different pH) containing Tween 80, Sodium Lauryl Sulphate (SLS) at different concentrations were used as solvents for this study. The saturation solubility of rofecoxib in the solvents were determined by continuous shaking of 50 mg rofecoxib in 50 ml of respective solvent in a closed conical flask at 37°C for 24 hours. After shaking the flasks were kept for 12 hours in an incubator at 37°C for equilibration. Then filtered samples were diluted suitably and assayed spectrophotometrically at 231 nm against blank. From the solubility data, the solubility of refecoxib in 900 ml of 5% w/v SLS in water was found to be approximately ten times of the solubility to the original dose of rofecoxib (50mg), satisfying the sink conditions. After incorporating SLS, the increase in solubility was larger in the case of water than that of 0.1 N HCL and phosphate buffer.

The performance of selected dissolution medium (900 ml of 5% w/v SLS in water) was confirmed by conducting the dissolution experiments of prepared and commercial formulations. The results of present study reveals that water containing 5% w/v SLS is a suitable dissolution medium with good discriminating power for routine *in vitro* dissolution testing of rofecoxib and its formulations.

A25 Formulation and evaluation of Ketoconazole antidandruff hair styling gel.

S.H. Nayak, P.D. Nakhat*, P.G.Yeole

Institute of Pharmaceutical Education and Research, Wardha 442 001 (M.S.)

Ketoconazole (KCZ) is alcohol soluble, broad-spectrum antifungal agent used in the treatment of variety of fungal infections. KCZ is widely used in hair shampoos for the treatment of dandruff. Shampoo produces temporary antidandruff effect for span of hours in a day on the scalp. Hence an attempt has been made for formulation of ketoconazole antidandruff hair styling gel, which may give antidandruff action for number of hours.

Hair styling gel of KCZ [F1 (0.5%), F2 (1.0%) and F3 (1.5%)] was prepared using Carbopol 940 (0.40%), Polyethylene Glycol (30%), Alcohol (30%) and Water (40%). Carbopol 940 used as a base former. Prepared hair styling gels were evaluated for physical characterization (viz. viscosity, consistency, spreadability and texture.), antimicrobial activity and stability studies. All the formulations showed compliance with acceptable limits. Formulation F2 showed maximum zone of inhibition. The same was compared with marketed shampoo (M1) containing 2%w/w KCZ and was found to be same in antifungal activity.

Formulation F2 was subjected to stability studies for three months and showed negligible changes in consistency, viscosity, spreadability and texture.

I.R. spectral studies confirmed no interaction between drug and polymer. Thus KCZ confirmed as a new drug of choice for the antidandruff hair gel.

A26 Studies on Semisolid Bases containing Ghee, Castor Oil, Liquid Paraffin

A.V. Asati, D.R. Mundhada* and P.G. Yeole

Institute of Pharmaceutical Education and Research, Wardha 442 001 (M.S.)

Ghee from animal origin (F1), castor oil from vegetable origin (F2) and liquid paraffin (F3) from mineral origin was used as vehicle for preparation of O/W cream containing Clotrimazole as a model drug.

The prepared creams were evaluated for Drug content, spreadability, consistency, texture, nature, homogeneity, pH and skin irritation. The stability study were performed for all the three formulations (F1, F2, F3) at different temperature upto 3 months at 75% RH. F1, F2, F3 were evaluated for *in-vitro* release of Clotrimazole by using modified Keshary Chien type diffusion cell. The antimicrobial activity of the developed creams F1, F2, F3 were determined on Staphylococcus aureus, *Candida albicans, Trichophyton rubrum* and *Malassezia furfur* by agar plate method. The same were compared with two marketed aqueous creams (M1, M2) containing 1%w/w Clotrimazole.

The results of drug content for all the creams complied to the official standards, neutral pH, satisfactory consistency, good spreadability, smooth texture, aqueous nature, good homogeneity and absence of skin irritation. The formulations were physically and chemically stable upto 3 months when stored at different temperatures.

Release rate of Clotrimazole from creams F1, F2 and F3 were very high as compared to that of cream procured from the market (M1, M2). The release rate of Clotrimazole from cream F1 indicated greater release out of all the creams. The order of drug release rate from various creams were as follows, F1 > F2 > F3 > M2 > M1

Formulations F1, F3 and M1 show zero order release rate kinetics where as F2 and M2 follow first order release rate profile. F1 also depicted higher antimicrobial activity as compared to the other formulations i.e. F2, F3 also show significant antimicrobial activity compared to that of the marketed preparation that is M1 and M2.

A27 Ethyl Cellulose Microspheres of Glipizide: *in vitro* and *in vivo* Evaluation for Parenteral Controlled Release

K.P.R. Chowdary, N. Koteswara Rao* and K. Malathi

Department of Pharmaceutical Sciences, Andhra University, Visakhapatnam 530 003.

Microspheres have been widely accepted as a means to achieve oral and parenteral controlled release. A number of different substances both biodegradable as well as non-biodegradable have been investigated for the preparation of microspheres. This study describes the preparation and evaluation of ethyl cellulose microspheres of glipizide with an objective of achieving parenteral controlled release and hypoglycemic effect over longer periods of time.

Ethyl cellulose microspheres of glipizide were prepared by an industrially feasible emulsion-solvent evaporation technique and the microspheres were investigated. The microspheres are spherical, discrete and free flowing. Encapsulation efficiency was in the range of 81-91%. Glipizide release from the microspheres was slow and diffusion controlled and extended over a longer period of 10 days and depended on core: coat ratio, wall thickness and size of the microspheres. Good linear relationship was observed between percent coat, wall thickness and release rate of the microspheres. In-vivo the microspheres produced a sustained hypoglycemic effect over 10 days in normal rabbits when administered subcutaneously and were found suitable for parenteral controlled release.

A28 Oral osmotic pumps for simultaneous delivery of theophylline and salbutamol

Prabakaran D.*, Paramjit Singh, K.S. Jaganathan and S.P. Vyas

Department of Pharm. Sciences, Dr. H.S. Gour University, Sagar 470 003. M.P.

Asthma, a chronic disease is treated by multi-drug therapy, which is vulnerable to incidences of side effects, poor patient compliance and slow improvement of patients. The general principle followed in the management of asthma is to maintain the pulmonary status of the patients as long as possible. The chemotherapy of asthma involved many drugs particularly salbutamol (a b–adrenergic agent) and theophylline in combination is found to be very effective. The draw backs associated with multi-drug theraphy of asthma can be reduced by development of an osmotically regulated multi-drug delivery system, which can deliver two drugs (theophylline and salbutamol) simultaneously. Three different formulations have been developed, i.e 1. simple controlled porosity system composed of mixture of choline theophylline and salbutamol sulphate. 2. push-pull system where upper layer containing specified amount of theophylline base mixed with HPMC (hydroxyl propyl methyl cellulose) and mannitol and lower layer containing specified amount of choline theophylline and salbutamol sulphate mixed PEO (poly ethylene oxide), which was used as hydrogel swellable layer and 3. push-pull system in which upper layer containing specified amount of theophylline base and salbutamol sulphate mixed with HPMC and lower layer

contained specified amount of choline theophylline mixed with PEO. *In vitro* drug release studies showed that satisfactory release profiles of both drugs upto 16 h except system 1, comparable to respective sustained release marketed products could be attained . The release kinetics of the formulations were determined and found to be osmotic pressure dependent and diffusion controlled. The developed systems can be used as once daily formulations for the simultaneous sustained delivery of theophylline and salbutamol, however, suitability and clinical significance of the systems have to be confirmed by *in vivo* bioavailability studies in appropriate animal/human models.

A_{29} Formulation and evaluation of bilayered bioadhesive buccal tablets of lisinopril

R.S. R. Murthy[a], M. M. Patel[b], Jayvadan patel[b*]

a. Pharmacy Department, M. S. University of Baroda, Vadodara

b. Shree S. K. Patel College of Pharm. Edu. & Res. Ganpat Vidyanagar, Kherva-382711

The buccal mucosa is a potential site for delivery of a drug into systemic circulation, avoiding first pass hepatic metabolism and premature drug degradation within g.i.t. Lisinopril is an effective anti-hypertensive agent, degraded by first pass hepatic metabolism and only 30% of the drug is absorbed orally. Thus there is an urgent need to develop dosage form through alternative routes for Lisinopril. The present study was aimed at developing buccal adhesive tablets of Lisinopril. Systemic absorption of the drug may cause an increase bioavailability of the drug, thus reducing frequency of dosing and decreased toxicity and other side effects. Bioadhesive bilayered buccal tablets of lisinopril were formulated based on the principle of unidirectional release from laminated matrix tablets. Tablets were prepared using a combination of bio-adhesive polymers like Carbopol 934 P. Hydroxypropyl methylcellulose (HPMC-K4M) and chitosan. Among different combinations Carbopol 934P, HPMC - K4M. and Chitosan mixed in a ratio of 3:4:1 gave the maximum percentage of drug release *in-vitro* without disintegration in 8 hrs. Bioadhesive strength was found to be 9.32 g. Adhesion time was greater than 6 h. Soluble excipients like polyethylene glycol-6000 and Mannitol were also included in the formulation. The concentration of Mannitol affected the drug release and bioadhesive properties. The kinetic exponent (n) was near to 0.85 indicating zero order drug release. The formulation was also subjected to in-vitro permeation studies and *in-vitro* swelling studies. The eptimized batch showed high *in -vitro* permeation (70%) and good swelling properties. The *in-vitro* studies in healthy volunteers and animals also showed good bioashesion. No drug irritation was observed in humans. A comparison study of *in-vitro* drug release of bioadhesive table with that of an oral tablet of Lisinopril showed that there was a significant increased in C_{max} and T_{max} values. Results of stability studies reveal that the formulation was stable for more than two years.

A_{30} Investigation of cyclodextrin complexation of nifedipine and its application in the design of controlled release tablets

K.P.R. Chowdary[1], G.K. Reddy[2] and S. Vijaya Srinivas[1*]

1. Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam

2. Dr. Reddy's Laboratories, Hyderabad

The objective of the work is to investigate the complex formation of nifedipine (N) with b-cyclodextrin (bCD) and hydroxypropyl b-cyclodextrin (HPbCD) to improve its solubility and dissolution rate and the feasibility of using these cyclodextrin complexes in the design of oral controlled release tablets.

Complex formation was investigated by phase solubility studies, which indicated the formation of a N-bCD (1:1 M) and N-HPbCD (1:1 M) inclusion complexes in solution with a stability constant of 121.9 M^{-1} and 253.7 M^{-1} respectively. The solubility of N increased linearly as a function of concentration of CDs. Solid inclusion complexes of N-bCD and N-HPbCD, prepared in 1:1, 1:2 and 1:3 ratios by kneading method, exhibited much higher rates of dissolution as compared to nifedipine. An increase of 20.6 and 42.9 fold in the dissolution rate of N was observed respectively with N-bCD (1:2) and N-HPbCD (1:2) complexes.

Matrix tablets of nifedipine (20 mg) were formulated employing N alone and N-bCD and N-HPbCD complexes using carbopol as matrix material. Slow, controlled and complete release of N over a period of 12 h was obtained from tablets formulated employing N-bCD and N-HPbCD complexes which was not possible with similar tablets formulated employing nifedipine itself. Drug release from these tablets followed zero order kinetics up to 85-90% release and the release was diffusion controlled.

Controlled release tablets of nifedipine were formulated as two layered tablets, with an immediately releasing layer consisting of N-bCD (1:3) or N-HPbCD (1:3) complex along with a superdisintegrant and a second sustained release layer consisting of matrix of N-bCD (1:3) or N-HPbCD (1:3) complex in carbopol. These two layered tablets gave release profiles very close to the theoretical SR needed for nifedipine based on its pharmacokinetics.

A31 Development and evaluation of floating drug delivery for celecoxib

Arora S*., Ali J., Ahuja A., Khar R.K.

Research Scholar, Dept. of Pharmaceutics, F/O Pharmacy, Jamia Hamdard, Hamdard Nagar, New Delhi 110 062

An attempt was made to improve the bioavailability of celecoxib, class II drug of BCS classification. This was done by enhancing the GI residence time by designing floating drug delivery system. Single unit capsules were formulated which upon administration would attain a density of less than that of the gastric fluids and would float. Thus the capsules would remain in stomach for a prolonged period of time. Different grades of the floating polymer Poly Ethylene Oxide (PEO) (grades-WSR 1105, WSR 301, WSR 303, WSR 60 K, and WSR N80), HPMC (K4 M, A4 M, K100 LV), sodium alginate and Eudragits (RL 100, S) were selected. Different ratios of the above said polymers were physically blended with 100 mg of celecoxib and filled in hard gelatin capsules (size 0). The capsules were immersed in 900 ml of citrate buffer pH 3 (simulating the pH of gastric contents of stomach in fed state) in USP paddle type apparatus at 50 rpm. The time for which the capsules remained buoyant was observed and was taken as the floating time. The polymer that showed the best floating behavior was taken for *in vitro* release studies. It was observed that PEO WSR 60K and PEO WSR 303, HPMC K4 M containing formulations showed the best floating behavior i.e. they were found floating for 12 hrs. Formulation containing Eudragit RL100 floated for 8 hrs. *In vitro* release studies carried out based on maximum buoyancy period, showed that formulation containing PEO WSR 60K gave 48.05% drug release while PEO WSR 303 containing formulations showed only 19 % drug release. Formulation containing HPMC and sodium alginate gave 57.4% drug release while formulation containing PEO WSR 60K and Eudragit RL100 showed *in vitro* drug release of 78.97% in 8hrs. Hence on the basis of buoyancy behavior and in vitro release studies it can be concluded that formulation containing PEO WSR 60K and Eudragit RL100 was the optimized formulation and can be taken up for further studies.

A32 Preparation and evaluation of diltiazem hydrochloride loaded albumin microspheres

Jani Girish K.[1], Chauhan Manish[1], Prajapati Vipul*[2]

1. Department of Pharmaceutics, L. M. College of Pharmacy, Ahmedabad 380 009
2. Department of Pharmaceutics, Shri Sarvajanik Pharmacy College, Mehsana.

Diltiazem hydrochloride (DH), a coronary vasodilator known as calcium channel blocker, is widely used in the treatment of angina pectoris, arrhythmias and hypertension. It has a short elimination half life ($t_{1/2}$ = 3 – 5 hours) and needs frequent dosing. To achieve several advantages over its sustained release tablets – the development of homogeneous monolithic drug delivery system (microspheres) is required.

In the present investigation, DH loaded albumin microspheres were prepared by w/o emulsion thermal cross-linking method and supplied in capsule. Aqueous albumin solution, light liquid paraffin (LLP) and span 60 were selected as a dispersed phase (DP), dispersion medium (DM) and surfactant respectively. During preparation different process variables like concentration and volume of DP, types and volume of DM, types and concentration of surfactant, thermal cross-linking temperature, time and stirring speed were evaluated and optimized. For DH loaded microsphere independent variables - Drug: Polymer (D: P) ratio, volume of DP and surfactant concentration and dependent variables - % drug loading were evaluated and optimized to 1: 1 (750mg: 750mg), 10ml 7.5 %w/v of aqueous albumin, 0.4 % surfactant by a 3^2 factorial design.

Optimized best batch of microsphere showed highest (79.20 %) drug loading with small spherical particle (GMD = 47.5 ± 0.5microns) by optical microscopy with moderate aggregation and used for further evaluation like *in-vitro* drug release and its stability. To prevent burst effect optimized best batch was coated with ethyl cellulose (optimum 7.5 %). *In-vitro* dissolution study from capsule revealed that microspheres sustained the release of drug up to 12 hrs as that from the market preparation and alone microspheres. Accelerated stability study (at 40° ± 2° C, 75 ± 5 % RH) for one month showed no significant change on release profile, physical characteristics and drug content.

A33 Preparation and *in-vitro* evaluation of ranitidine hydrochloride magnetic microspheres by emulsion – solvent evaporation method

Latha S*, and Pal T.K

*Ultra college of Pharmacy, Madurai– 625 020, India.

Targeted release ranitidine hydrochloride magnetic microspheres were prepared by emulsion - solvent evaporation method using Eudragit RS - 100 and ethyl cellulose as the matrix. The prepared magnetic microspheres were spherical with diameter in the range of 50 – 300 µm. The effects of drug: polymer ratio and stirring rate during the preparation and the drug release rate was investigated. Increase in the concentration of the polymer decreases the drug release rate significantly. The most retardant effect was obtained using Eudragit RS - 100. With the increase in the stirring rate; magnetic microsphere size was

decreased and the drug release rate was increased. Release data were examined kinetically. Dissolution data indicated that release followed by Higuchi matrix model kinetics.

A34 Formulation development of fast dissolving Nabumetone tablets

Joel Peres Ashtamkar*, S.S. Bhalerao, Namita Joshi

K M Kudnani College of Pharmacy, Worli, Mumbai 400 018

Fast dissolving tablets have gained importance especially for poorly soluble drugs. These systems improve dissolution of the drug thereby increasing its absorption rate and bioavailability. Nabumetone is a non- steroidal anti-inflammatory drug (NSAID) used to treat rheumatic and inflammatory conditions. Nabumetone is a non-acidic prodrug, which is absorbed through duodenum and undergoes extensive first pass metabolism in liver to principal active metabolite 6-methoxy-2-naphthylacetic acid (6-mna). Nabumetone is practically insoluble in water, which is responsible for its poor dissolution rate and slow onset of action.

The work presented here deals with preparation, optimization and evaluation of tablets. Different batches of tablets without drug were prepared by wet granulation method using diluents like lactose, starch and MCC; binders like starch paste 10% (1-5%), CMC in water 10% (1-5%) and PVP in alcohol 10% (1-5%); and Superdisintegrants like sodium starch glycolate (2-8%), croscarmellose sodium (2-5%) and crospovidone (2-5%). the tablets prepared were studied for granule yield, particle size distribution, Carr's index, hardness of granules, tensile strength of tablets and disintegration time. Three best batches, which were giving satisfactory results, were selected and tablets containing Nabumetone (500mg) were prepared. These tablets containing Nabumetone were evaluated for the above mentioned tests; in addition *in-vitro* release studies by dissolution test was performed. *In-vitro* release profiles were compared with the marketed Nabumetone tablets. Furthermore stability studies and bioavailability studies are in progress.

A35 Micro porous drug delivery of Theophylline for colon targeting

Samanta, M. K., Prudhvi Raju, D., Atul A. Daroi*, Vijay Wagh, Yashwant Dhanorkar and B. Suresh

Dept. of Pharmaceutics, J.S.S. College of Pharmacy, Elkhill Road, Ootacamund 643 001.

Drug delivery selectively to the colon through the oral route has been the subject of new research initiatives. Micro porous drug delivery of theophylline was developed for the colon specific drug delivery. The dosage form was designed based on Poly (DL Lactide Co glycolide) (PLGA, 50:50) polymer coated with environmentally sensitive Eudragit L 100 and S100 polymers combinations (1:1,1:2, 2:1, 1:3, 3:1, 1:1.5, 1.5:1). PLGA based micro porous dosage forms of theophylline were prepared by modified phase separation method with different drug - polymer ratio (1:2, 1:4 and 1:8) to obtain porous nature. Thereafter porous microcapsules were coated with Eudragits by using emulsion solvent evaporation technique for colon targeting. Preformulation study confirmed on optimum solubility for Eudragit L 100 and S100 (1:1.5) at pH 6.6 to 7.0. The microcapsules were tested for physicochemical properties, particle size, surface morphology, drug loading capacity, % yield and in vitro drug release evaluation. Dissolution study was carried out by half dilution method for a period of 24 hr with buffer simulation to GIT and maximum 91.35% drug release was found. The average particle size was in between 28.62 to 42.65 microns. The SEM showed that these microcapsules were spherical and consisted of porous surface. The drug loading efficiency was found to be 48.09% to75.34%. The result for dissolution of Eudragit coated formulation indicated that the drug was released after 7-8 hr of experiment and thereby expected to target to the colon via oral route. Further comparative evaluation of micro porous dosage form was done using commercially available SR tablet and CR capsule. It is concluded that Eudragit coated PLGA porous microcapsule showed better targeting efficacy than uncoated microcapsule and marketed SR and CR products. Coated microporous drug delivery of theophylline may be better alternative for the treatment of nocturnal asthma.

A36 Formulation and characterization of Clozapine solid lipid nanoparticles

Kopparam Manjunath*, V.Venkateswarlu

University College of Pharmaceutical Sciences, Kakatiya University, Warangal 506 009. A.P.

Solid lipid nanoparticle drug delivery systems (SLN) possess additional advantages and avoid disadvantages of other colloidal drug delivery systems. Clozapine a lipophilic an atypical neuroleptic agent with low extrapyramidal side effects has very poor bioavailability (27%). Solid lipid nanoparticle (SLN) delivery systems of Clozapine have been developed by hot homogenization of melted triglycerides (trimyristin, tripalmitin and tristearin) and aqueous phase followed by ultrasonication. Process and formulation variables have been studied and optimized. Particle size and charge measurements were made with Malvern Zetasizer. Effect of stearylamine on particle size and charge were studied. Entrapment

efficiency of Clozapine was determined by ultracentrifugation method. Differential Scanning Calorimetry (DSC) and Powder X-ray diffraction (PXRD) studies were performed to characterize state of drug and lipid modification.

Stable SLN formulations of clozapine having mean size range of 60 to 380 nm and zetapotential range of -23 to + 33 mV were developed. Optimum particle size was obtained with 1 % poloxamer. Stearylamine induced optimum zetapotential to clozapine SLN and also particle size. More than 90 % clozapine was entrapped in SLN. DSC and PXRD analysis showed that clozapine is dispersed in SLN in an amorphous state.

A37 Development and characterization of niosomes for oral immunization

Sanyog Jain* and S. P. Vyas

Sanyog Jain, C/o, Shri Mahesh Kirana Bhandar, Katra Bazar, SAGAR (M.P.) 470 002

Non-ionic surfactant based vesicles (niosomes) were prepared, characterized and evaluated for their potential use in oral immunization. Niosomes were prepared by reverse phase evaporation method. Bovine serum albumin was chosen as the model antigen. Niosomes were coated with a modified polysaccharide o-palmitoyl pullulan (OPP) to protect them from bile salt caused dissolution and enzymatic degradation in the gastrointestinal tract. Prepared niosomes were characterized for their size, shape, entrapment efficiency and stability in simulated gastric fluid. The immune stimulating activity was studied by measuring serum IgG level following oral administration of the OPP coated niosomes in albino rats and results were compared with conventional uncoated niosomes and plain alum adsorbed BSA given by oral as well as intraperitoneal routes. It was observed that OPP coated niosomes could produce better IgG levels as compared to plain uncoated niosomes and plain alum adsorbed BSA. The plain uncoated niosomes could also produce significantly higher IgG levels as compared to equivalent BSA-alum based oral immunization. The significance of OPP coated niosomes as potential adjuvant for effective oral immunization was established.

A38 Spray dried powders as nasal absorption enhancers of verapamil hydrochloride

Grace Rathnam

CL Baid Metha College of Pharmacy, Thorapakkam, Chennai 600 098.

In recent years, the intranasal route of administration of drugs with low oral bioavailability has been extensively evaluated. Verapamil hydrochloride undergoes extensive first pass metabolism and has an oral bioavailability of 15 – 20 %. Drugs absorbed through the nasal route can directly enter the systemic circulation before passing through the hepatic ciculation. The major difficulty in administering drugs intranasally is their low bioavailability due to mucociliary clearance, poor mucosal membrane permeability and enzymatic degradation. These problems have been overcome by co-administrating with penetration enhancers and bioadhesive materials. Microcystalline cellulose(MCC) was chosen as it provides prolonged residence time due to its insolubility and has absorption enhancing effect due to its calcium binding capacity. Among the different systems like microspheres, nanoparticles, powders, solutions and gels widely studied, powders have greater application. Spay drying technique was chosen to produce an intense union between the drug and MCC in the ratio 1:1 using two solvents. The formulations were characterized for morphology by Scanning Electron microscopy, particle size, moisture content, water uptake, drug excipient interaction, drug loading, in vitro dissolution and permeation and nasal bioavalability.

The spay dried powders have an optimum particle size between 16.8 – 19.5 microns. Water uptake which is essential for the tight junction opening is between 30 to 35%. Drug loading is between 31 to 52.5%. The formulations show complete dissolution at the end of 4 hours, and between 92 to 95.5% permeation at 4 hours. The nasal bioavailability studies carried out in rabbits for the formulation and compared with the pure drug powder showed a significant increase in bioavailability from 2.8% for the drug powder to 42.5% for the formulation.

A39 Liposomal drug delivery systems of Vitamin E Acetate

Pommi Subbashini *, Rupali Meshram, Dr. Amrita Bajaj

C.U.Shah College of Pharmacy, SNDT Women's University, Mumbai 400 049

Vitamin E and its derivatives protect the skin from damage caused by U.V radiation. It acts as an antioxidant. The aim was to develop liposomes as carrier systems for trandermal delivery of Vitamin E.

The liposomes of vitamin E acetate were prepared by lipid film hydration method. A 2^2 factorial design was used to study the effect of cholesterol (X_1) and lipid concentration (X_2) on entrapment efficiency of the liposomes. Higher entrapment efficiency (55%) was obtained with 5% lipid and 0.25% cholesterol concentrations. This optimized batch was selected for TEM, NMR, and DSC studies.

The liposomal gel prepared with 2% Carbopol 934P NF was found with good consistency and

acceptable feel. The *in-vitro* release studies were conducted using animal skin and semipermeable parchment paper attached to Keshary Chein diffusion cells. The drug release from liposomal dispersion was found to be 80.55% and whereas liposomal gel released only 66.25% through parchment paper after 6hrs. Plain vitamin E acetate gels and liposomal gels were subjected to *in-vitro* release studies using guinea pig skin for 24hrs.The drug release from plain gel was 46.98% and the release was further retarded in liposomal gel to 27.74%. The Draize patch test did not show any irritancy potential in rabbits and healthy human volunteers.

Liposomes were found to control the rate of delivery and extend the duration of effect of vitamin E acetate. The drug release was further retarded in gel matrix. Hence the liposomal gels of Vitamin E acetate provide a safe and effective transdermal application.

A40 Optimization of sustained release pellets containing sintered wax

Kunal Agrawal*, Reena Singh, Poddar S.S.

K M Kundanani College of Pharmacy, Dr. R.G. Thadani Marg, Worli, Mumbai 18.

Sustained release (SR) dosage forms aims at giving prolonged and efficient delivery of therapeutic agents with predictable and reproducible drug release kinetics. Multiple unit SR dosage form offers various advantages over unit types. Amongst multiparticulates, pellets offer greater therapeutic and technological advantages. Pellets were prepared by extrusion-spheronization. Waxes, well-known rate retardants, was included in an effort to slow drug release.

In present work this process has been endeavored not only to reduce the particle size but also to obtain them as microscopic spheres. Work was also aimed at incorporation of Carnauba wax in pellets without use of additional binders e.g. starch or PVP and to determine whether sintering i.e. melting and fusion of neighboring wax particles would aid in matrix formation.

Lab work included :

1. Size reduction of carnuba wax. (a) Grinding (b) Emulsification
2. Pellet formation of Theophylline drug.
3. Sintering of these pellets.

These pellets were subjected to the process of sintering. Sintered and unsintered pellets were evaluated for various parameters like SEM, friability index etc.

This work highlighted that with large size wax particles, pelletization was difficult which affected sintering and drug release thereafter adversely. Grinding of wax did not yield fruitful results. Fine micron range carnauba wax obtained by emulsification facilitated uniform distribution of wax and also pellet formation and it's sintering. This also eliminated the use of starch binder. This absence of binder improved subsequent thermal sintering.

Sintering of these matrix pellets retarded the drug release and these sintered pellets showed good handling characteristics.

This exercise reveals that by selecting proper carnauba wax-drug ratio, sintering time, sintering temperature, an effective controlled release dosage form could be formulated.

A41 Graft polymerization of the chitosan hydrogels in controlled drug delivery

D.Ravikumar*[1], P.Parimala[1], N.S.Chandrahekar[2], P.K.Kulkarni[2]

1. Karnataka Antibiotics and Pharmaceuticals Ltd. Bangalore 560058. (Formulation Research and Development)
2. J.S.S. College of Pharmacy, S.S.Nagar Mysore - 570015

Hydrogels are water –swollen, crosslinked polymeric structures produced by the simple reaction of one or more monomers, hydrogels especially, have become excellent carriers for release of drugs and bioactive macromolecules either in their swollen equilibrium state or as dynamically swelling systems .A new method was adopted for the preparation of fast responding hydrogels with microstructure with high swelling ratio. This was prepared by graft copolymerization of poly(dimethyl siloxane) (PDMS) on to CHITOSAN(CS) ,pH sensitive hydrogels were obtained based on natural polymer and a synthetic polymer. These PDMS substituents provide the basis for hydrophobic interactions that contribute to the formation of hydrogels. Various graft hydrogels were prepared ratios of chitosan and PDMS. Swelling behavior of these prepared hydrogels was studied by immersion in different buffer concentrations (1,2,3,4...11) characterization of the samples Fourier transform infrared spectroscopy (FTIR) sample CP 12shown the highest swelling at the ratio of chitosan:PDMS(1:2) among (1:2,1:3,1:4,4:1) .It has shown time-dependent, temperature –dependent and pH dependent swelling behavior. Hence this ratio will be the key proportion for using the hydrogels as drug carriers.

A42 Various approaches in *in-vitro* dissolution enhancement of rofecoxib

M.C.Gohel, R.K.Parikh, M.M.Soniwala*

Department of Pharmaceutics & Pharmaceutical Technology, L.M.College of Pharmacy, Ahmedabad - 09.

Rofecoxib(R) is selective COX-II inhibitor and used in the treatment of osteoarthritis and related disorders. It is insoluble in water and hence exhibits poor dissolution profile. The aim of present study was to improve the solubility and dissolution rate of drug by formulating solid dispersions with various hydrophilic carriers (PEG 6000, PVP K 30, Eudragit E 100) and inclusion complex with α-cyclodextrin (α-CD). Drug was estimated by UV spectrophotometry using 0.1 N HCl as dissolution media. The solid dispersions/inclusion complexes were characterized by IR and photomicrograph studies.

Rofecoxib forms Eutectic mixture with PEG 6000 and glass solution with PVP K 30 and Eudragit E 100. PVP K 30 was found to be more effective in increasing the drug dissolution, compared with PEG 6000 and Eudragit E 100.The inclusion complex of rofecoxib and α-CD were prepared by physical, co-grinding and kneading method. The dissolution was obtained as high as 75% in 1:5 R: α-CD molar complex prepared by kneading method. The theoretical prediction for the use of α-CD as a dissolution enhancing agent was also performed. For further dissolution enhancement the combination of two dissolution enhancing agent i.e. PVP K 30 and α-CD were used. 3^2 factorial design was conducted to optimize the proportion of both the carriers. The Q_{60} of the optimized batch was 97.917 %. The tablet from the optimized formulation was then compared with the existing marketed products and was found to have better dissolution.

A43 Lipid nanostructures incorporating anticancer agent : A novel solvent dispersion technique for the preparation thereof

L. Harivardhan Reddy* and R.S.R. Murthy

Drug delivery research laboratory, Pharmacy Department, Faculty of technology and Engineering, The M.S.University of Baroda, Vadodara-390002, India.

A novel and simple solvent dispersion technique for the preparation of lipid nanostructures was developed. This technique is superior to the existing methods of lipid nanoparticle preparation such that, it avoids the possible metal shedding involved with ultrasonication, avoids thermal exposure of lipids and drugs involved in hot melt homogenization, and avoidance of large quantities of organic solvents involved in the preparation with solvent injection method. The nanostructures were characterized by particle size analysis, differential scanning calorimetry and transmission electron microscopy. The influence of various process factors such as rate of lipid addition, stirring rate, homogenization pressure and cycle time on final particle size were determined. The formulation factors such as surfactant concentration, lipid composition on the size and entrapment efficiency of nanostructures was also investigated. Homogenization pressure and cycle time greatly influenced the final particle size. Homogenization of the nanodispersion at 15000psi for 5 min resulted in very small particles of 164 nm diameter. 2 % w/w surfactant concentration was found optimum for obtaining smaller sized nanostructures (289 nm). The lipid composition with greater lecithin quantities resulted in higher entrapment and smaller size of nanostructures. A 5 % loading of Etoposide (anticancer agent) into the lipid nanostructures was achieved. DSC thermogram of drug-free nanostructures did not exhibit any thermal events. *In vitro* drug release study of nanostructures was performed in pH 7.4 phosphate buffer. The results of kinetic analysis reveal that the release of etoposide from lipid nanostructures followed Higuchi equation. Lipid nanostructures incorporating etoposide with smaller size coupled with their sustained release characteristics could be a beneficial delivery system for the targeted delivery applications for cancer therapy.

A44 Evaluation of *Gum damar* as a microencapsulating agent

V.C. Bafna*, U.V. Barabde, D.M. Morkhade, P.M. Satturwar, S.V. Fulzele and S.B. Joshi

Department of Pharmaceutical Sciences, Nagpur University, Nagpur 440 033.

Gum Damar is obtained naturally from *Dipterocapaaraceae* tree of Indonesian origin. It is used as stabilizer and emulsifier in paints and inks. It is widely used as aromatic emulsions in food and cosmetics industry.

The objective of the present work was to evaluate natural resin *Gum Damar* for its microencapsulating property. Diclofenac sodium was used as a model drug. Modified solvent evaporation technique was used for preparing microcapsules. The drug-gum solution in dichloromethane: alcohol (3:2) was sprayed in continuous stirring preheated liquid paraffin (dispersion media) with 0.5 mm nozzle spray gun. The microcapsules were dried and collected after filtration under vacuum. The two variables studied were effect of atomization pressure (40psi and 50psi) and effect of drug : gum ratio (1:1, 2:1 and 3:1) on evaluatory parameters. Microcapsules prepared were evaluated for surface topography (scanning electron microscopy), encapsulation efficiency, particle size, *in vitro* drug release and drug release kinetics. Zero order, first order and Higuchi square root models were applied to drug release data.

Encapsulation efficiency was highest with 1:1 ratio of drug and gum and found to give sustained drug release upto 12 hours. Atomization pressure showed no significant effect on particle size. Microcapsules obtained were spherical as expected. Higuchi square root model adequately fits the release data of microcapsules with all drug : gum ratios studied.

The results of investigation encourage *Gum Damar* as a novel sustained release microencapsulating material. Future plans include evaluation of uncovered formulation and process variables in microencapsulation with the proposed material.

A45 A novel biodegradable polymer for drug delivery

Agnihotri S.M.* and Vavia P.R.

University Institute of Chemical Technology, Matunga, Mumbai 400 019.

Polymers prepared from glycolides and lactides from aliphatic polyesters class are attractive polymers that can be used in biomedical and pharmaceutical applications. Reasons for the growing interest in this type of degradable polymers is that their physical and chemical properties which can be varied over a vide range by co-polymerization and advanced macromolecular architecture. A new PLGA-based copolymer (PLD-1) has been investigated as encapsulating material for drug delivery. Free films of PLD-1 were cast by solvent evaporation technique. In in-vitro degradation tests, the copolymer PLD-1 showed a 31.73% degradation after 6 weeks in buffer pH 7.0 at 37°C and exhibited high degradability towards trypsin and lipase-Q enzyme. Nanoparticles of PLD-1 were prepared by multiple emulsion and solvent evaporation method using diclofenac sodium, as a model drug. Nanoparticles were prepared by varying the drug: polymer ratios (1:10, 1:5, and 1:2). Prepared nanopaticles were characterized for particle size, drug content and *in-vitro* drug release. Good reproducibility in preparation of diclofenac sodium loaded PLD-1 nanoparticles was demonstrated with mean average particle size in the range of 123-262 nm and very narrow polydispersity (0.035-0.21). X-ray studies showed that the crystallinity of the drug, copolymer and polymeric systems remained unchanged; this study reveals that there is no interaction of the drug with the polymer. All drug loaded polymeric systems exhibited a biphasic release behavior.

A46 Formulation of taste masked reconstitutable oral suspension of Cefpodoxime Proxetil by complexation with ion exchange resins

Ketan Ranch*, A.R. Koli, C.S. Chauhan, M.P. Wagh, V. K. Mourya.

N.D.M.V.P. Samaj's College of Pharmacy, Gangapur Road, Nasik-2

Non-bitter complexes of Cefpodoxime Proxetil were prepared using ion exchange resins by Batch Process. Tulsion-344, Tulsion -3434 and Micpol-1061 were used as ion exchange resins. Drug Resin complex (1:3.5) of Tulsion -344 was selected and formulated into a dry oral suspension for reconstitution using a flavored, sweetened, buffered and a preserved base and sodium carboxymethyl cellulose as a suspending agent.

The reconstituted suspension was kept under refrigerated condition for fifteen days. The stability of the suspension after reconstitution was evaluated after fifteen days. Evaluation for various parameters of the reconstituted suspension was done by measuring viscosity, pH, density, sedimentation volume, drug assay, and palatability. The reconstituted suspension was found to be stable for fifteen days at refrigerated condition. The reconstituted suspension was found to be stable in terms of sedimentation volume, viscosity, ph, drug assay, and palatability as compared with other marketed formulations.

Bitter taste masking ability of the preparation was maintained and the reconstituted suspension was found to be palatable due to complexation of drug with Tulsion-344 resin and due to adequate sweeteners and flavors.

A47 Formulation and evaluation of gastric retentive systems of metformin hydrochloride

K. Hima Sankar*, Khushwant Singh Yadav, L. Srinivas, G. V. Murali Mohanbabu and K. V. Ramana Murthy

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam 530 003

Gastric retentive controlled release dosage forms may produce higher bioavailability and superior effects for drugs with a narrow absorption window, compared to immediate release and oral controlled release dosage forms. This is because gradual release of the drug from this dosage form in the stomach results in a continuous and prolonged input of the drug to the main absorption sites located in the small intestine. In the present study an effervescent floating drug delivery system for metformin hydrochloride with a prolonged gastric residence time was developed. The pharmaceutical composition in the form of tablets comprises gas generating component (sodium bicarbonate), rapid swelling agent (super disintegrant) and a rate-controlling polymer (guar gum).

All the prepared tablets were able to float within 30sec. (lag time) and floated up to more than 24hrs(duration of floating). The floating lag time mainly depended upon the concentration of effervescent agent present in the matrix. Although effervescent agent played a major role in bringing up buoyancy, a significant change in the lag time was observed by incorporation of super disintegrant. It is observed that the matrices with low concentration of polymer showed faster release compared to matrices with higher concentration of polymer. Initially drug released at a faster rate due to the presence of effervescent agent and super disintegrant and also due to slow rate of hydration of polymer. Although the release rate mainly

depended on the concentration of the hydrophilic polymer, the entrapped gas within the hydro gel also influenced the release of the drug from the matrix. The drug release followed diffusion mechanism with first-order release kinetics.

A48 Chitosan (low density) floating tablets; formulation and optimization

E. Valsaraj*, M.A. Kuriachan

Department of Pharmaceutics, College of Pharmaceutical Sciences, Medical College, Trivandrum, Kerala.

Chitosan is a natural basic polysaccharide and has been reported to be useful for many pharmaceutical preparations. Chitosan has great potential for being used as a suitable carrier in the sustained and controlled release drug delivery systems. The gastro retensive systems which increases the gastric retention time of the dosage form at the stomach and upper part of small intestine and hence suitable for the drugs having site specific absorption from the above sites. Various approaches have been tried to retain the dosage form in the stomach as a way of increase the overall retention time.

In this study a novel floating tablet formulation with a prolonged gastric residence time was developed utilizing the low density and gel forming property of chitosan. It consist of mixing drug and chitosan and compressed using a rotary tabletting machine. The floating property was attained by optimizing the process parameters such as weight, compression pressure and thickness while maintaining the average hardness of 5.5 kg. These floating tablets were then coated with ethyl cellulose solution which consists of polyethylene glycol-4000 as pore forming agent after evaluation like hardness, weight variation, friability and floating property studies.

These tablets have showed excellent floating property *in-vitro* in simulated gastric fluid with slow gel formation for more than 24 hours. They found attached to the container wall which shows the mucoadhesive property of the tablets. Any deviation from the optimized formula was found to provide profound deviation from the floating characteristics and hardness.

These findings indicated that the floating and gel formation property of chitosan tablets in acid pH provide and attractive alternative for the controlled delivery for drugs having site specific absorption from stomach and upper part of small intestine. The main advantage is that almost double the quantity of drug than that of chitosan can be used here without affecting the floating property.

A49 Studies on rheological properties of selected natural hydrogels

Kulkarni G.T.*, Gowthamarajan K, Rohan D., Reddy L.N. and Suresh B.

Department of Pharmaceutics, JSS College of Pharmacy, Rocklands, Ootacamund - 643 001 (TN)

The apparent viscosity of polysaccharide hydrogels from *Tamarindus indica, Plantago ovata* and *Ocimum basilicum* were calculated using flow curves obtained using a multipoint viscometer. The rheological properties describing the overall flow behaviour of hydrogels were correlated with their concentrations. The effect of pH on the viscosity was also investigated.

The obtained data was plotted as rate of shear Vs shearing stress, log–log plots and concentration of hydrogel against viscosity. The results showed that all the hydrogels exhibited thixotropy at all the concentrations used in the study. The apparent viscosity was found to be highest at pH 6, for *Plantago ovata* and *Ocimum basilicum hydrogels,* whereas, it was found to be highest at pH 7 for *Tamarindus indica* hydrogel, indicating better hydration at that particular pH. The rheological data suggested that the hydrogels follow non-Newtonian pseudoplastic behaviour. The log viscosity exhibited first order relationship with concentration.

A50 Evaluation of sodium carboxy methyl guar gum in the formulation of microencapsulation

Pallavi Waghale*, S. Parida, G. Trivedi, S. Srujankumar, V. Kale, R. Alaspure

Lonic cross linking of Sodium carboxymethyl guar gum with metal ions like Ca^{++} and Ba^{++} is reported. Guar gum is derivatized with carboxymethyl group by the method described in literature. When a solution of sodium salt of carboxymethyl guar gum containing drug is dropped into metal ion solution insoluble microbeads are formed. The amount of drug retained, morphology of resulting beads and the subsequent release of drugs (in vitro dissolution) was determined. It was found that divalent barium was superior as cross linking agent when compared to Ca^{++} or Al^{+++} ions. The optimum concentration of Ba^{++} required to provide maximum retention of drug was found to be 10%. The beads have shown the release of almost all the encapsulated drug over the period of six hours.

A51 Cyclopentenyl fatty acid impregnated collagen based dermal scaffold

Kishore Babu M., Mary Babu *Grace Rathnam

C.L. Baid College of Pharmacy, Jothi Nagar, Thorapakkam, Chennai - 600 096

Leprosy is the chronic granulomatous infection caused by *Mycobacterium leprae,* affecting skin, mucous membrane and nerves. *Erythema nodosum leprosum,* the secondary leprotic infections are due to the leprae infections which is characterized by acute exaberations during the course of leprosy. Recent reports have claimed that the wounds in leprosy patients healed faster when the oil of *Chaulmoogra* was administered locally. The active constituents of the oil used for the present study are the cyclopentenyl acid of *Chaulmoogra* oil namely *Chaulmoogric* acid and traces of hydnocarpic acid which are found to be more effective in the treatment of secondary leprotic ulcers. Collagen was chosen to form the scaffolds as it exhibits bio-degradability, weak antigenicity and superior biocompatibility. The aim of this present work is to develop and characterize a collagen based dermal scaffold for the treatment of secondary leprotic ulcers. The collagen was isolated from calf skin according to the procedure described by Piez et al. Chaulmoogric acid was isolated from medicinal grade chaulmoogra oil by saponification following the barium acetate method. The fatty acid extracted was characterized by FTIR, HNMR, CNMR and Mass Spectroscopy.

Collagen scaffolds aids in wound healing and avoids the stickiness of the oil and as the drug is delivered for a prolonged period eliminates the frequency of dressing. The Chaulmoogric acid impregnated collagen scaffold was prepared by soaking 1 g collagen in 40 ml of 0.,05 M acetic acid overnight till it is completely solubilized. To this viscous solutions 200 mg of the isolated acid was added and cast on moulds and dried at 40° to form the dry thin sheets. The scaffolds were characterized for drug distribution homogeneity and *in vitro* release. The prepared scaffolds have good homogeneity and show a release of 20% drug at 12 hours and 50% at the end of 72 hours.

A52 Enhancement of dissolution rate of flurbiprofen

V. Ganesan*

S.B.College of pharmacy,Anaikuttam, Sivakasi (TN) 626 130.

Solid dispersions of Flurbiprofen in polyvinyl pyrrolidone (PVP), hydroxy propel methyl cellulose (HPMC), hydroxy propel cellulose (HPC) and polyethylene glycol 6000(PEG) and solvent deposited systems on lactose, soluble starch, microcrystalline cellulose (MCC), Dicalcium phosphate (DCP),silica gel and their selected tablet formulations were investigated with an objective of enhancing the dissolution rate of flurbiprofen. A marked enhancement in the dissolution rate and dissolution efficiency of flurbiprofen was observed with all solid dispersions and solvent deposited systems. Among the carriers used in solid dispersions PVP gave highest enhancement (19 fold) in the dissolution rate of Flurbiprofen at 9:1 ratio of drug and carrier and in the case of solvent deposited systems MCC and DCP gave an improvement of 13:1 and 17:5 fold in the dissolution rate of flurbiprofen respectively as1:2 ratio of drug and excipient when compared to flurbiprofen itself. The solid dispersions in PVP and HPMC and the solvent deposited systems on MCC and DCP could be formulated into tablets. These tablets, apart from fulfilling the official and other specifications, exhibited higher rates of dissolution and dissolution efficiency values.

A53 Use of microwave to achieve sustained release of water soluble drugs

Chivate Amit*, Shajahan A, Dolly Talreja, Poddar S.S.

K. M. Kundnani College of Pharmacy, Mumbai 400 018.

A sustained release dosage form has numerous advantages over conventional ones. There are many techniques available to sustain the delivery of drugs. Here the use of microwave has been attempted to retard the release of drugs. Microwave has two effects, direct & indirect. The indirect effect is, the generation of heat. Both these effect are useful for improvement in retardation of release of drugs from polymer mixture.

Theohylline was chosen as model drug. The polymer system used was made with gelatin & Eudragit RLPO. Granules were formed, which were exposed to microwave for different time periods at same intensity. These granules were also analyzed with FT-IR. The granules showed no signs of degradation. Polymer-Polymer interactions were noted. The dissolution results indicated that the more the duration the granules were exposed to microwave the more was the retardation of release. Thus, just by controlling the time of exposure we could control the rate of drug release from the polymer mixture. Microwave proved to be advantageous over the noxious chemicals usually used for crosslinking or interactions.

A54 Formulation and Evaluation of Nicotine Buccal Patches

Srinivasa Rao, M*. Chadrashekar, K. and Madhusudan Rao, Y.

University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, AP, India.

This investigation mainly relates to the design and evaluation of buccal patches of Nicotine for smoking cessation. Solvent casting method was followed to prepare the patches. The polymer used to control the drug release is HPMC 5 cps. Patches were prepared with polymer in different drug polymer ratios.

Studies such as partition coefficient, *in situ* permeation, buccal absorption tests of drug, drug release studies, moisture absorption, mucosal adhesion and quality control tests of patches were carried out following standardized procedures. *In situ* penetration and buccal absorption study revealed that nicotine could penetrate through oral cavity and penetration was gradually increasing. Drug partition increased steadily, from pH 6 to 7 patches formed were with plasticizer concentration of 10-25%. Buccal patches with drug polymer ratio (1:30) were suitable for *in vivo* studies. Moisture absorption studies concluded that the patches erode quickly and could be useful for immediate release and low concentration of HPMC 5 cps may not be suitable to formulate buccal patches.

The *in vitro* release study indicated drug release was inversely proportional to polymer concentration. With the polymer concentration of 1:50 near zero order release was seen. Release rate data was further utilized to develop polynomial models with the drug load of the patches which could be used to optimize the desired release profile.

The study indicated that a suitable buccal drug delivery system can be developed to improve its bioavailability and an optimized buccal patch is expected to provide better smoking cessation. Such system could be successfully used a once a daily therapy for smoking cessation. Moreover there is a scope for the development of bioadhesive buccal patches o nicotine and to carryout further studies.

A_{55} Design and evaluation of controlled release hydrodynamically balanced system of theophylline with HPMC $K_{100}M$ using sintering technique

Kalpana Swain*, Satyanarayan Pattnaik
K. A. Chowdary, P. Suresh

College of Pharmaceutical Sciences, Berhampur, Orissa.

HBS system with sintering technique is an approach to increase the gastric residence time of drugs in stomach. This system is designed for site specific oral drugs with low bulk density than gastric fluid so as to buoyant the dosage form in stomach to increase the residence time of the drug.

In the present investigation, an attempt has been made to design hydrodynamically balanced drug delivery system for theophylline using HPMC $K_{100}M$ polymer with solvent casting sintering technique.

The various batches of matrix tablets of theophylline designed with HPMC $K_{100}M$ in different drug : polymer ratio incorporating increasing concentrations of sodium bicarbonate under direct compression method, were exposed to different time periods under saturated acetone vapour system for sintering.

The tablets of hydrodynamically balanced system so designed were evaluated for physical characteristics, drug content, floating time, floating lag time, etc. The study reveals that the formulations of HBS of theophylline formulated has exhibited a floating lag time of less than 5 minutes and floating time of more than 22hrs. The studies on IR spectra showed C=O group at 1718.5 cm^{-1} for theophylline.In comparision with pure drug the absorption peak of the spectra for theophylline in treated matrix showed no shift and no disappearance of characteristic peaks suggesting that there is no interaction between drug and HPMC $K_{100}M$ or no degradation in theophylline molecule or no reaction between HPMC $K_{100}M$ and theophylline.

The *in-vitro* release studies of the HBS was compared with the release characteristics of commercially available established brand of oral sustained release formulation of theophylline.

The kinetics of drug release was found to be of first order and the mechanism of drug release followed Higuchi's diffusion model. A significant correlation was observed between the release of theophylline from the sintered tablets with that of the drug : polymer ratio & exposure time of sintering. It is concluded that the drug : polymer ratio of 10 : 1 sintered for a period of 1hr has exhibited optimum release of drug as compared to the release studies of commercial SR tablet of theophylline.

A_{56} Formulation and evaluation of a topical gel - metronidazole

Bishnu Bibha Mohanty*, R. Kalaiselvan, K. Rajshekhar

Department of Pharmacy, Annamalai University, Falma Laboratories Ltd, Bangalore.

Metronidazole is a synthetic nitroimidazole derivative which is an anti-bacterial and antiprotozoal agent. Metronidazole is active against gram-negative anaerobic bacteria. Metronidazole is a potent anti-infective agent specifically active against anaerobic microorganism. Usually it is indicated for the treatment of skin disorders like malodorone post surgical prophylaxis. Prefomulation study of Metronidazole was done. The first step in the development of Metronidazole was screening of the solvent and polymer. The next step of development was to

concentrate on study of the effect of nonionic surfactant on Metronidazole penetration through the animal skin.The final selected nonionic surfactant utilized to optimize the formulation.In vitro release study was of the optimized gel formulation was conducted with animal skin. In the last part of the development the skin retention time was investigated taking animal model. Final formulation was made by utilizing seven gelling polymer with solvent system like water , alcohol and propylene glycol.

A57 Nanosized triglyceride particles of varying chain lengths: evaluation of physicochemical properties and their potential as drug carriers

Nishant Bakshi*, L. Harivardhan Reddy
R.S.R Murthy

Pharmacy Department, Faculty of Technology and Engineering, The M.S.University of Baroda, Vadodara-390002.

Lipid nanoparticles of triglycerides with different chain lengths (Tributyrin – C4 and Tristearin – C18) were prepared by hot-melt homogenization technique and characterized by particle size analysis and Differential Scanning Calorimetry (DSC). The influence of cooling temperature on the recrystallization pattern of lipids in dispersion was studied. Various formulation factors such as surfactant and co-surfactant concentration, homogenization, pressure and cycle number on particle size and distribution was investigated. Tributyrin formed nanoparticles of larger diameter even at 5%w/w surfactant concentration, whereas a combination of Tween 80 and PluronicF127 at 5%w/w resulted in very small particles with diameter ranging between 48 to 149 nm. Greater homogenization pressures upto 15000 psi resulted in smaller particles. The increase in cycle number increased the particle size and smaller nanoparticles were obtained with the first cycle itself (132 nm). This is probably due to particle coalescence as a result of development of electrostatic forces on particle surface, due to prolonged exposure of particles to high shear forces. Influence of cooling temperature of nanodispersion on various thermal events was investigated by DSC. The bulk lipid showed two melting endotherm at 53°C and 60 °C corresponding to the α- and α- polymorph respectively. The recrystallization of lipid from nanoemulsion occurred much below the melting point and room temperature, indicating its presence in solid state rather than any other forms such as supercooled melt. The samples were cooled down at different rates to 4°C, 25°C and 45°C. A shift in melting endotherm towards lower temperature was observed in dispersions cooled to 4°C, compared to the dispersions cooled to 25°C and 45°C. Incorporation of Tamoxifen citrate into triglyceride nanoparticles was performed by dissolving in lipid prior to emulsification. The DSC thermograms of drug loaded nanoparticles showed the absence of melting endotherm of tamoxifen (at 145°C), indicating its presence in amorphous state in nanoparticles after entrapment. The release of Tamoxifen from tristearin nanoparticles was 8% after 24 hours. The smaller size of triglyceride particles along with the sustained release properties would be a potential targeted delivery system for cancer therapy.

A58 Studies on dissolution enhancement of nimesulide: response surface optimization (RSM) of drug release characteristics

Naveen Ahuja and Bhupinder Singh*

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh -160 014

Poorly water-soluble and highly permeable BCS class II drugs are associated with poor rates of drug absorption leading to inadequate and inconsistent bioavailability. Accordingly, their oral absorption is limited to the dissolution rates. Further, response surface optimization techniques are being widely used to optimize the drug release characteristics thus saving a great deal of time, money and professional expertise.

In the current study, some water-soluble carriers were investigated for their dissolution improvement potential in case of nimesulide, a BCS Class II drug. These carriers encompass, conventional hydrotropes, polyethylene-polypropylene glycol block copolymers (LutrolÒ F127 & F68), self-emulsifying macrogol fatty acid esters (Gelucires®) and natural hydrogel (BNA). Central Composite design was employed to optimize drug release characteristics viz. $t_{80\%}$, rel_{15min}, $\%DE_{15min}$. Preoptimization studies revealed promising results with LutrolÒF127 and BNA. Thus, these two carriers were further employed as factors at 3 levels each. Various dispersions formulated by hot-melt technique in randomized manner as per experimental design, were evaluated for in vitro dissolution. RSM optimization was performed using Design-Expert® 6.0.6 software. Selected optimal compositions were formulated as checkpoints, and results critically compared with those predicted using RSM.

For all LutrolÒ F127 and BNA dispersions, release rate of nimesulide was significantly improved compared to pure drug and physical mixtures. Appropriate balancing between levels of the two factors is imperative to acquire adequate rel_{15min}, $\%DE_{15min}$ coupled with lower values of $t_{80\%}$. RSM optimization yielded results with high degree of prognosis. Further, DSC, XRD and SEM studies on the chosen optimum formulations portrayed distinct loss of drug crystallinity.

A59 Multiparticulate sustained release pellets for the management of Manic depressive illness

Poddar S.S*, Lalla J.K.

K.M. Kundnani College of Pharmacy, Worli, Mumbai 400 018.

Inspite of arrival of newer drugs, lithium carbonate is one of the drugs of choice for long mood stabilization in patients suffering from manic depressive illness. Though SR tablets of this drug is available, many are found to be having not quite realistic and desirable release profiles. It is known that pellets are more likely to lead to therapeutic success than tablets in SR context. Thus the objective of present exercise was to formulate SR capsules composed of pellets having suitable immediate release and zero order sustained release capabilities helping in the generation of logistic invivo results.

Two types of pellets were prepared through the standard process of extrusion-spheronization, namely immediate release and sustained release. Immediate release spherules were constructed using optimized portions of MCC and PVP. They were coated employing Eudragit RSPO. For the coat optimization computer generated response surfaces were used. The invitro release profiles of the formulation were linked with their invivo performance in human volunteers. Through the process of evolutionary operations the most desirable formula was arrived at. The formulations when passed through the rigors of accelerated stability testing following ICH protocols were found to well retain their qualities.

The work was successful in arriving at suitable capsule formulation of lithium carbonate, which would prove to be superior for the patients of mania.

A60 Prolonged systemic delivery of diltiazem hydrochloride using mucoadhesive multivesicullar liposomes

Kishore B. Chalasani,[a] Abhay S. Chauhan,[a] Akhlesh K. Jain,[a] *Sarath K. Yandarpu,[a] S. Ramakrishna,[a] S. K, Jain[b] and Prakash V. Diwan[a]

a. Pharmacology Division, Indian Institute of Chemical Technology, Hyderabad-7

b. Dept. of Pharmaceutical Sciences, Dr. H.S. Gour University, Sagar (MP), 470003

Lipid based sustained release system is one of the approaches for the delivery of drugs. The multivesicular Liposomes (MVLs) are the versatile structures in contrast to multilamellar vesicles (MLVs), encapsulates large aqueous phase, which shown to have significant loading of hydrophilic drugs, such as proteins and their release for prolonged periods up to 1-2 months. Diltiazem hydrochloride is being used in various cardiovascular complications that need repeated administration with prolonged regimens. The reason which necessitates viable controlled delivery include 1) extensive pre - systemic degradation leading to a low oral bioavailability and 2) short half - life requires 3-4 times daily administration. The present study characterizes usefulness of a novel mucoadhesive MVLs for controlled systemic delivery via ocular route. MVLs of 35 mm (average size) with a high loading (60%) were prepared by double emulsification process. The systems were coated with chitosan to give a positively charged surface for mucoadhesion to corneal layer, and the coating was confirmed by zeta potential studies. In vitro studies indicated significant mucoadhesion of coated formulations and diltiazem was released for a period of 1-2 week compared to 1-2 days of MLVs. Effective plasma diltiazem level were found up to 15 days, after ocular instillation of formulations compared to non coated (1-2) days and plain drug solution (12 hrs) vis a vis, significantly high bioavailability was found. The potential of this system, therefore, opens an avenue for controlled systemic delivery of hydrophilic drug via mucosal routes.

A61 Potential of Tf-coupled PLGA nanoparticles for peroral insulin delivery

Kishore B. Chalasani, Abhay S. Chauhan, Akhlesh K. Jain, Sarath K. Yandarpu*, S. Ramakrishna and Prakash V. Diwan

Pharmacology Division, Indian Institute of Chemical Technology, Hyderabad 500 007

Inspite of encouraging results, a result of decade of research in both academic and industrial levels, the goal of oral protein delivery especially insulin remains a challenging area. Transferrin, an iron binding protein, is absorbed through duodenum by receptor mediated endocytosis. A previous study shows transport of insulin-Tf conjugates across the CaCo2 cell layers, a mechanistic model for trans intestinal transport. However, such conjugates may not withstand proteolysis in the gut and uptake may not be sufficient for therapeutic response since insulin has short biological half life.

The present work characterizes the efficacy of PLGA nanoparticles (50:50;85:15) coupled with transferrin. The PLGA nanoparticles are prepared by double emulsion solvent evaporation technique with high insulin loading. Intregity of encapsulated insulin was determined by Elisa method. Transferrin coupling was carried out at 4°C in presence of EDAC after NHS activation. Conjugation was confirmed by TNBS, Zeta potential and XPS analysis. In vitro enzymatic study showed that insulin is protected against proteolysis. The conjugated particles are administered orally to the

STZ induced rats at dose of 15 IU /Kg body weight. The system showed the maximum blood glucose reduction of 42.3 +3.2 (% initial) with in 4th hour. The onset of action was observed at 2nd hour of administration and has shown considerable reduction until 8th hour. Further characterization is needed for the effective transport of such systems across the intestinal epithelium.

A62 Transdermal studies of flurbiprofen - β cyclodextrin complex using xanthan gum as reservoir

S. S. Shyale, S. M. Shantakumar, V.V.S. Rao, G. Sudhir, K. Bharath Kumar*

Dept. of Pharmaceutics, V. L. College of Pharmacy, Raichur - 584 103, Karnataka

Xanthan gum gel (5%) can be used as a reservoir for drugs like flurbiprofen in TTS. Since flurbiprofen is a poorly soluble and less bioavailable in systemic circulation, its beta cyclodextrin complex (1:1) was prepared to improve its solubility. The complex was incorporated into 5% Xanthan gum get or 5% carbopol - 934 gel and then in vitro permeation studies across depilated albino rats was studied. Also permeation through membrane - moderated systems of EVA 2825 was studied.

The physical characteristics of the films like thickness and water vapour transmission were evaluated by standard techniques. *In vitro* permeation studies were carried out in Keshary Chien diffusion cells at 50 rpm and at 37± 0.5°C across depilated albino rat skin.

The results showed that the thickness remained uniform as indicated by low percentage coefficient of variation. The films were found to transmit water at both 56% RH 84% RH, percentage water vapour transmission was found to follow zero order kinetics. In vitro permeation studied across depilated albino rats skin showed increased flux values for betacyclodextrin complexes as compared with simple 5% gel reservoirs, with or without rate controlling membrane EVA - 2825. All the formulation obeyed Higuchi's square root diffusion. Also 5% xanthan gum reservoir gels provide better steady state fluxes than carbopol gels. Since human skin is three times greater barrier than the rat skin, at least one third of reported flux logically would be obtained across human skin. Since the flux value reported are for 1 cm^2 patch a 25 cm^2 would definitely give enough steady state flux in human begins, making 5% (w/w) xanthan gum reservoir gels a potential carrier as a transdermal gel with or without rate controlling membrane EVA -2825.

A63 Formulation Development of Controlled Release Lysozyme Micro- and Nano particles using biodegradable polymers

Madhusudhan S[2*], Amulya.K.Panda[1] Yogesh K. Katare[1], Manna.P.K.[2], Dhanapal.C.K[2] and Manavalan.R[2]

1. Product Development Cell, National Institute of Immunology, New Delhi – 110 067
2. Department of Pharmacy, Annamalai University, Annamalai nagar, Tamil Nadu – 608 002

The Lysozyme, an antibacterial enzyme used in the treatment of mouth and respiratory infections was selected as a model protein because of easy availability and versatility. Microparticles and nanoparticles of lysozyme were prepared using biodegradable Poly (D, L) lactic acid (PLA) and Poly lactic Glycollic acid (PLGA 50:50; 45 KD) polymers by Multiple emulsion (w/o/w) solvent evaporation method and the resultant particles were evaluated for morphology, encapsulation efficiency and drug release pattern. By changing the ratio of polymer to lysozyme from 12.5 to 50 times and using PLA & PLGA polymers, 8 different formulations of microparticles and two nanoparticles were prepared. The SEM images were taken for selected formulations F2, F6, LN1, LN2 and the images reveal uniform spherical shape with occasional roughness on the surface. Few PLGA microparticles were also ovoid in shape. The particle size of microparticles and nanoparticles ranges from 2 to 20 mm and 400 to 1000 nm respectively. In case of PLA microparticles encapsulation efficiency was found to increase with the increase of polymer to drug ratio, with an optimum ratio of 2:50; while in case of PLGA microparticles, this ratio had no influence in encapsulation efficiency and all PLGA microparticles show higher entrapment efficiency (up to 89%) than PLA microparticles, suggesting hydrophilic PLGA as better polymer for encapsulation. Formulation with drug: polymer ratio of 2:50 shows gradual and constant release up to 30 days.

A64 Pharmacodynamics of Ampicillin sodium prepared Transdermal patches in an *in vitro* infection model against Escherichia coli Strain

J.Bagyalakshmi, A.S.Williams*, T.K.Ravi, R. Manavalan[1], P. K. Manna[1]

Institute of Pharmaceutical Technology, Annamalai University, Chidambaram.

The activity of ampicillin - sodium against lactamase producing *E.coli* has been questioned. Therefore, in this study, the killing activity of ampicillin

sodium was investigated in an *in vitro* infection model which stimulates human pharmacodynamics. Ampicillin sodium was made into a transdermal patch with different kinds of polymers such as Sodium alginate, cellulose acetate pthalate, 3% hydroxyl propyl methyl cellulose 3% chitosan and 3% carboxy methyl. Cellulose and drug releasing capacity was studied through killing curves or colony forming units. The drug contained in the various patches were subjected for a 24 hrs study, from which it was found out that 3% hydroxyl propyl methyl cellulose, chitosan, cellulose acetate pthalate, sodium alginate. The whole procedure was carried out at 37°C.

A65 Volume of Entrapment - A better parameter for optimization of liposomal formulations

Girish Bende, * Gopal Das and R. N. Saha

Research Scholar Pharmacy Group, FD III, Birla Institute of Technology and Science, Pilani 333 031 Rajasthan

Liposomes are lyotropic liquid crystal mainly composed of amphiphilic bilayer entrapping a central aqueous core. They are becoming popular among formulation scientists due to revelation of their potential use in protein and peptide drug delivery during last decade along with their various advantages like structural flexibility in size, composition and bilayer fluidity, where their ability to incorporate large variety of drugs including hydrophobic compounds gives cutting edge. Extent and the site of their binding depend on both electrostatic and hydrophobic interactions.

The volume of the aqueous space within the liposomes is one of the most important factor influencing drug entrapment. Moreover, this parameter gives key information in process development and optimization of such formulations. Liposomes provide several sites of interactions and binding for foreign molecule. Along with the molecular weight and solubility data, the volume of entrapment not only provides explanation for supermolecular siting of drug molecules but also gives brief idea about the size of vesicles.

In present investigation an attempt has been made to opitimize loading volume by studying of entrapment. Here, Liposomal formulation of Fluorescin was prepared using phosphotidyl choline and cholesterol, where different loading volume was given with the same concentration, keeping all other processing parameters constant. The formulations were estimated for Fluorescein content by using validated analytical method.

The volume of entrapment was constant for different formulations and is a better parameter for process optimization, as larger this volume of aqueous core, the greater the amount of polar drugs that can be encapsulated. Loading volume can be optimized on the basis of volume of entrapment which results in better efficiency of entrapment.

A66 Influence of composition of carrier lactose on the site of drug delivery in the lung from budesonide dry powder inhaler formulations in vitro

Mahavir Chougule*, Ambikanandan Misra

Pharmacy Department, Faculty of Technology & Engineering, Kalabhavan, MS University of Baroda, Gujarat, India.

The purpose of this investigation was to study the influence of composition of lactose on the site of drug delivery in the lung using budesonide as a model drug. The addition of ternary component to interactive mixtures has been investigated to improve the efficiency of lung deposition from Dry powder inhaler formulation. DPI formulation comprises of coarse lactose as a carrier and micronized drug. Carrier lactose was a mixture of more than one grade of lactose for delivery of drug at targeting site in the lung. The formulation & process variables were optimized by 3^2 factorial designs with two factors at 3 levels. The factors considered are the lactose to drug (BS) ratio and time of blending. Formulations (ternary mixtures TM) composed of carrier lactose (CL) (63-90ìm), intermediate sized lactose (IML) (17.059 ìm VMD) and budesonide (BS) (4.477 ìm VMD)were prepared by hand blending technique. The formulations which consists of CL, IML & BS with a fixed carrier to BS ratio of 61.5:1 w/w using 1%, 5% & 10%w/w of IML. In addition a binary mixture composes of CI toBS ratio of 61.5:1 w/w was also prepared as a control. The formulation with different adding sequences were also been prepared and the in vitro drug delivery behavior was studied by measuring fine particle fraction (FPF) using twin stage impinger (TSI) as per British pharmacopoeia after aerosolization at 60 l m^{-1} via a Rotahaler®. The FPF, FPD, %dispersibility & % emission were also been evaluated. All formulations prepared by changing composition of carrier lactose with IML produces a significantly higher fine particle fraction than that of the control. The content uniformities of all the mixtures were found to be within the range of (±10%). It was also found the adding sequence affects FPF of BS. The BS delivery to lung BS delivery from the dry powder inhaler formulation was improved significantly by changing the composition of carrier lactose. It was concluded from the studies that the properties of carrier lactose, concentration of IML (1-10%w/w) & blending sequence have significant influence on targeting drug at different sites in the lungs. Properties of carrier lactose such as size, size distribution surface morphology, surface rougosity, electrostatic &fundamental forces, shape, flow properties and moisture content etc. were found to be play a significant key role in targeting the drug at different sites of the lungs, mainly the alveoli in case of asthma.

A67 Preparation, optimization and *in-vitro* drug release of nimodipine loaded PLGA nanoparticles

Ashishkumar K. Mehta*, Krutika K. Sawant, Yogesh H. Raichandani, Bhupendra G. Prajapati

Faculty of Technology and Engineering Pharmacy Department, Donor's Plaza in Front of University Main Office, Fatehgunj, Baroda 390 002

Nimodipine (NIM) is widely used calcium channel blocker. Although it is completely absorbed following oral administration, it shows extensive first pass metabolism and oral bioavailability of the drug is low and variable (3-30%) and frequent dosing is required. It is intravenously administered for enhancement of bioavailability but requires continuous infusion.

Biodegradable Nanoparticles can be successfully used for enhancement of drug bioavailability along with various sustained and controlled release applications. PLGA (poly (D, L, -lactide-co-glycolide) a widely studied biodegradable polymer was selected for its well known sustained and controlled release applications. The aim of the present study was to formulate biodegradable Nanoparticles containing nimodipine loaded in (poly (D,L, -lactide-co-glycolide) (PLGA). The effects of formulation parameters (Drug: Polymer ratio (X1) and the concentrations of surfactant (X2)) were investigated using a 3^2 factorial design. The optimum conditions were judged on the basis of particle size, size distribution and encapsulation efficiency. The laser light scattering and U.V analysis showed that the size and encapsulation efficiency greatly depended on the Drug: Polymer ratio and concentration of surfactant. The results indicate that, an increase in Drug: Polymer ratio from 1:5-1:15% markedly increases the encapsulation efficiency of nimodipine in the Nanoparticles. It was also found that, an increase in surfactant amount from 0.1-0.3% w/v markedly decreases the particle size of the Nanoparticles. Determination of particle size revealed that the use of 0.3%w/v of surfactant concentration and a Drug: Polymer ratio of 1:10 resulted in particle size below 200nm. The Nanoparticles prepared at a Drug: Polymer ratio of 1:10 and surfactant concentration of 0.3% was found to be optimum formulation. The optimized batch was characterized by X-ray photoelectron spectroscopy (XPS) for surface chemistry and, differential scanning calorimeter (DSC) for thermo gram properties.

In-vitro diffusion study of the optimized batch was conducted using modified dialysis method, which exhibited sustained release kinetics for the drug.

A68 Controlled systemic delivery of indomethacin using membrane moderated cream formulations based transdermal devices

Ramarao P. Kishore, B. Chalasani, Abhay S. Chauhan, Akhlesh K. Jain*, Sarath K., Yandarpu and Prakash V. Diwan

Pharmacology Division, Indian Institute of Chemical Technology, Hyderabad 500 007, India

The objective of the present study is to design a viable and practically effective transdermal devices of indomethacin cream based drug reservoirs and suitable rate controlling membranes. Two cream vehicles include 1) a much lipophilic base (F1) and 2) a cream formulation containing predominant aqueous phase (F2) were chosen to study the influence of vehicle nature and role of permeation enhancers that increases thermodynamic activity, to provide diffusible pieces of drug to skin. Rate controlling membranes of cellulose acetate (CA) and Ethyl Cellulose (EC) with polyvinyl pyrollidine (PVP) and hydroxypropyl methyl cellulose (HPMC) were fabricated for these cream based drug reservoirs. *In vitro* skin permeation study showed a flux of 7.0 ± 0.9 mg / cm^2 hr from F2 compared to 4.3 ± 0.6 mg / cm^2 / hr from F1 and its increases with increase in drug concentration from 2% to 6% w/w thereafter difference was no longer significant. All the three rate controlling membrane decreases the flux of indomethacin across the rat abdominal skin. A significantly higher flux was observed with CA :PVP (2:1) membrane (9.6 ± mg / cm^2 hr) compared to ethylcelullose films containing PVP and HPMC as a hydrophilic constituents. Effective plasma concentrations of indomethacin are maintained up to 24 hrs where as oral formulation showed only up to 8 hrs. Although the systemic level between both EC films differ insignificantly, PVP film showed a better pharmacokinetic profile. The pharmacokinetic data after oral and transdermal administration of indomethacin indicated that the parameters such as C_{max} t_{max} and MRT of indomethacin were significantly different ($p<0.05$) from each other. The pharmacodynamic performance of the transdermal devices exhibited good anti-inflammatory activity over a period of 24 hrs compared to orally administered indomethacin. In vivo studies indicates the superiority (0.67 - 0.83) were significantly lower compared to oral indomethacin (7.86). Further, enhancement may be achieved with other classical enhancers / enhancement strategies in such devices employing aqueous cream vehicle and the optimum membranes.

A69 Formulation & Optimization of Flutamide Liposomes by 3^2 factorial. design

Manish Umrethia*, Amit J. Raval, Abhay Goti, Hitesh Dodiya, R.S.R Murthy

New Drug Delivery System Labouratory, Pharmacy Department, Donor's Plaza, The M.S.Uni. of Baroda, Fatehgunj, Vadodara-2

The present study deals with the study of the effects of two independent variables Drug: Lipid molar ratio (X1) and Phosphotidylcholine (PC): Cholesterol (Chol) molar ratio(X2) on % entrapment efficiency (%EE) of Flutamide (FLT) liposomes using 3^2 full factorial design, the derivation of reduced second order polynomial equation to construct response surface and contour plots to obtain predetermined %EE and development of FLT liposomes with maximum %EE by conventional thin film hydration technique. Based on 3^2 factorial design, nine batches of FLT liposomes were prepared by conventional thin film hydration technique. Prepared liposomal batches were evaluated for %EE (response variable). The %EE and the transformed values of independent variables were subjected to multiple regressions to establish a second order polynomial equation (full model). F statistic was applied to reduce polynomial equation (reduced model) by neglecting non-significant ($p>0.05$) terms. The reduced polynomial equation was used to develop response surface plot to show the effects of X1 and X2 on %EE and contour plot to obtain various combinations of values of two independent variables (X1 and X2) at predetermined values of %EE. The conformity of the established equation was checked by preparing three batches three times taking values of independent variables from contour plots for prefixed value of %EE. Prefixed %EE value taken for designing the experiment and results obtained experimentally were compared using 't' test and difference between experimentally obtained and theoretically calculated values of %EE and was found to be statistically non-significant ($p>0.05$). The present study establishes the role of derived equation and plotted contour plot in predicting the values of independent variables for preparation of FLT liposomes by conventional thin film hydration technique.

A70 Complexation: a novel approach for Improving drug content uniformity

Darshan K. Parikh and Sunil S. Jambhekar

Department of Pharmaceutical Sciences Massachusetts College of Pharmacy & Health Sciences, Boston, MA 02115.

With the advent in science large numbers of potent compounds are discovered. The uniform distribution of these agents, particularly low dose drug, in the solid dosage form is a real challenge to formulators. Failure to achieve homogeneity would result into either a subpotent or superpotent formulations, both being undesirable. Therefore, the main objective of the present work is to evaluate the utility of drug-hydroxypropyl b-cyclodextrin (HPbCyD) inclusion complex in improving drug distribution and, therefore, the drug content uniformity in powder blends using furosemide as a model drug. Method: Complexes between drug and HPbCyD, in various molar ratios (1:1, 1:2, and 1:3), were prepared by solvent evaporation method and characterized using IR, DSC X-ray diffraction. Samples of drug-HPbCyD complex or physical mixture (PM), and drug-lactose PM were milled and fraction passing through 80-mesh sieve and retained on 200-mesh sieve was collected. These samples were mixed with CellactoseÒ, in a Hobart mixer, for a specified time period, samples were collected from various locations of the mixer, and the drug content was determined. Results: The results of IR spectroscopy, DSC and X-ray diffraction clearly indicated the formation of inclusion complex between a drug and HPbCyD. The blend uniformity data showed that drug-HPbCyD complex was able to disperse the drug more uniformly throughout the powder blend compared to the physical mixture (PM) Furthermore, it was observed that various molar ratios of drug-HPbCyD complex did not show significant difference in the drug content uniformity; suggesting a formation of 1:1 molar complex between drug and HPbCyD. Conclusion: Incorporation of a low dose drug through the inclusion complex appears to be a potential approach for improving the homogeneity of powder blends and, therefore, the drug content uniformity for the low dose drug.

A71 Co-processing of a ductile material with a brittle material: A combination for optimizing tabletting properties of directly compressible fillers.

Parag Shah and Sunil S. Jambhekar

Department of Pharmaceutical Sciences Massachusetts College of Pharmacy & Health Sciences. Boston, MA 02115, USA.

The possibility of using b-CyD, as a directly compressible filler, has recently shown considerable promise due to its greater compressibility compared to other commonly used fillers. The limitations of presently available b-CyD are inadequate flow property and lubricant sensitivity. It is postulated that these limitations may be overcome by coprocessing b-CyD, a ductile material, with a-lactose monohydrate, a brittle material. Such an approach will yield a powder mixture with an optimum compressibility with minimum stress relaxation and lubricant sensitivity because of the combine effect of ductile and brittle components. The main objective of this research is to evaluate such a coprocessed material prepared by using a-lactose monohydrate and b-CyD.

Lactose and b-CyD were coprocessed in the ratios of 75:25, 60:40 and 90:10 by using three methods: 1) Minigranulation: Granules were prepared by using 15,20,25 and 30% w/w of water as a granulating liquid and dried at 40,60 and 90°C in a tray drier. 2) Co-drying: Slurry for the above ratios were prepared by using 50 and 75% w/w of water and codried in a tray drier at 40, 60 and 90°C. 3) Spray drying: Lactose and b-CyD were dissolved in water and spray dried in a fluid bed dryer. The excipients thus prepared were characterized and compared with marketed products for essential tabletting properties

The chosen methods and ratios did not show significant difference in the angle of repose; however, coprocessed materials showed better and/or comparable flowability with commercially available fillers. At 75:25 and 60:40 ratios, the coprocessed excipient exhibited better compactibility and compressibility than all other marketed coprocessed products. It has acceptable lubricant sensitivity, dilution capacity and faster dissolution rate when compared with commercial products.

The improved flowability, compressibility and dissolution properties of the coprocessed materials are attributed to the synergistic effect between lactose and b-CyD.

A72

Effect of vehicles on the transdermal delivery of nimesulide across hairless rat skin *in vitro*

R.J. Babu* and Mandip Singh

College of Pharmacy and Pharmaceutical Sciences, Florida A and M University, Tallahassee, FL 32307,USA

Nimesulide (4-nitro-2-phenoxymethane-sulfonamide) is one of the newer non-steroidal anti-inflammatory agents and has very low water solubility (0.022 mg/ml). The purpose of this study was to investigate the effect of various vehicles on the in vitro permeation of nimesulide across hairless rat skin. The vehicles used in the study were: polyethylene glycol 400 (PEG-400), propylene glycol (PG), isopropyl myristate (IPM), ethanol:PG (1:1) Labrasol®, Transcutol®, Phosal®, water, ethanol, ethanol:water (1:1), PG:water (1:1), ethanol:PEG (1:1), ethanol:water (8:2), and isopropanol:water (8:2). The skin permeation studies were carried out using Franz diffusion cells and phosphate buffered saline (PBS) with 10% polyethylene glycol (PEG). PEG was included to enhance the solubility of nimesulide in PBS to maintain sink conditions. The permeation samples were collected using Microette® automatic sampling apparatus (Hanson Research Corporation, Chatsworth, CA, USA). The solubility of nimesulide was found to be as high as 206.0 mg/ml in PEG and as low as 0.022 mg/ml in water. Analysis of variance (ANOVA) of flux data of nimesulide with various vehicles showed that vehicles have a significant effect on the permeation rate of Nimesulide ($P < 0.001$). Similarly the permeability coefficients of nimesulide with different vehicles were significantly different with various vehicles ($P < 0.001$). Ethanol, TranscutolÒ, LabrasolÒ and IPM showed similar permeation rates and the differences among different vehicles were not statistically significant ($P < 0.05$). All other vehicles showed skin permeation rates, which were significantly, lower than ethanol ($P < 0.01$). There was no correlation between the flux and permeability coefficient values indicating that vehicles have variable effects on the hairless rat skin to induce skin barrier changes for nimesulide. Some of the vehicles (E.g. PEG, PG, ethanol:PEG, ethanol:PG and PG:water) even though increased the solubility to a greater extent than other vehicles, they showed poor flux and permeation coefficient values indicating high affinity of nimesulide with these vehicles as well as weak interaction with skin to reduce the skin barrier function. In conclusion, ethanol, Transcutol®, Labrasol® and IPM may be considered as potential vehicles for percutaneous absorption of Nimesulide.

B$_1$ A β-Galactoside prodrug of doxorubicin for application in antibody-directed enzyme prodrug therapy

D. H. Krishna, D. R. Krishna, and A. R. Rao

Medicinal Chemistry Research Division, University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, AP, India

Anthracycline antibiotics, particularly doxorubicin and daunorubicin, have been used extensively in the treatment of human malignancies. However cardiotoxicity and multidrug resistance are significant problems that limit the clinical efficacy of such agents. One of the rational design to avoid these complications is prodrug approach, activation of them in required site of action. In this context we synthesized doxorubicin prodrug having *para*-substituted benzyloxycarbonyl groups as spacer group between galactose and anthracycline moieties.

We present here a doxorubicin prodrug that is activated by β-galactosidase.The approach is based on the use of certain *para*-substituted benzyloxycarbonyl groups as bioreversible amine protecting agents. These agents function as a spacer between galactose and anthracycline moieties. Only after enzymatic cleavage did spontaneous self decomposition of this spacer occur to release the drug (**3**).

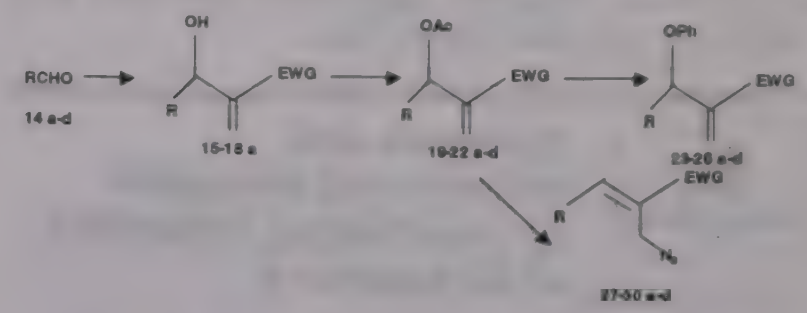
B$_2$ Derivatization of heterocyclic scaffolds through solid phase systhesis

Madhvi Sisodia, S. Batra and R. K. Agrawal

Shivaji Nagar, Bhopal, Madhya Pradesh 462 016

In the process of lead finding and optimization, many thousands of compounds are simultaneously generated using combinatorial techniques. The libraries can be prepared as mixtures (pooled libraries) or as collection of single substances in separate vessels (discrete libraries or arrays). The synthesized substance may exist free in solution or be supported on a solid phase. The most typical methodology for the preparation of pooled libraries is based on solid phase synthesis for peptide libraries. However, with the increasing demand to obtain pure compounds the focus has shifted to parallel synthesis where only one compound is synthesized in each well either through solid or solution phase chemistry.

The BH reactions of different benzaldehydes including 5-isoxazolecarboxaldehydes (14a-d) were carried out to furnish the BH adducts (15-18 a-d) following reaction were proceded (Scheme). The structure of these products was confirmed on basis of analytical and spectroscopic data.



This work has highlighted the fact that synthetic strategy optimized in the solution phase is easily transferred to the solid phase thereby providing the bench-markers for assessment of the purity of products obtained through solid phase and the quality of the chemical library. Since the solution phase chemistry confirmed that phenols undergo S_N2'-S_N2' reaction while the azides give S_N2' reaction only, it was easier, to optimize these reactions on solid support and characterize the products. These synthetic strategies can be extended towards the generation of chemical library of the heterocyclic scaffold (such as isoxazole). From the literature precedence and the earlier work reported, the isoxazole derivatives included in this report might show antimalarial and antithrombotic activities. The substituted isoxazoles are also considered to be important building blocks in the construction of new molecular systems for various reasons.

B$_3$ Studies in synthesis of Elacridar Analog

Dandekar V.D.*, Joshi A. A., Viswanathan C. L.

The Bombay College of Pharmacy, Kalina Mumbai–400 098.

In the present work an analog of Elacridar with very close structure characteristics was synthesized. The process developed is novel and involves simple starting materials. The emphasis is on developing an economically viable process.

Synthesis of Elacridar analog 9,10-dihydro-9-oxo-N-[4-[2-(1,2,3,4-tetrahydro-6',7'-dimethoxyisoquinolin-2-yl)ethyl]phenyl]-4-acridinecarboxamide involved alkylation of 6,7-dihydroxy-1,2,3,4-tetrahydroisoquinoline with 2-(4-nitrophenyl) ethyl bromide to get an intermediate, which was then methylated to 6',7'-dimethoxy-2-[2-(4-nitrophenyl) ethyl]-1,2,3,4-tetrahydroisoquinoline. The nitro group was then reduced to corresponding amine by using ammonium sulfide or tin and hydrochloric acid to get 4-[2-(6',7'-dimethoxy-1,2,3,4-tetrahydroisoquinolin-2-yl) ethyl] benzenamine. The amine and acridone-4-carboxylic acid were then condensed by using DCC to get the final Elacridar analog. The intermediates involved were also synthesized from simple substrates.

Progress of all reactions was monitored by thin layer chromatography. The compounds were characterized by melting point, infrared and ^{1}H NMR spectroscopy. Reaction steps were optimized with respect to yield and reaction time.

B4 Synthesis and antimicrobial evaluation of n-methylated derivatives of Dichotomin-A

M.Himaja*, Atish Sahu, M. V. Ramana, D. Satyanarayana, E.V.S. Subrahmanyam, K. Ishwar Bhat

Department of Pharmaceutical Chemistry, NGSM Institute of Pharmaceutical Sciences, Nanthoor, Mangalore-575005, Karnataka, India.

Dichotomin-A is a natural cyclic hexapeptide isolated from the roots of *Stellaria dichotoma* along with four other dichotomins (B-E) by Hiroshi Morita in 1996. Studies have shown that introduction of an N-methyl group into one of the amino acids of cyclic peptides significantly increased the antimicrobial activity as compared to the parent compound. Prompted by this, an attempt has been made to synthesise N-methylated derivatives of Dichotomin-A by the solution phase technique of peptide synthesis.

In order to synthesise, the molecule Cyclo[Thr-Phe-Leu-(N,O-dimethyl)Tyr-Val-Gly] was disconnected into three dipeptides:Boc-Gly-Thr-OMe (1), Boc-Phe-Leu-OMe (2) and Boc-(N-CH_3,O-CH_3)Tyr-Val-OMe (3) The dipeptide (1) and (2) were coupled using DCC and N-methylmorpholine (NMM) after appropriate deprotection to get the tetrapeptide: Boc-Gly-Thr-Phe-Leu-OMe (4). The tetrapeptide (4) and the dipeptide (3) were deprotected and coupled to get the hexapeptide Boc-Gly-Thr-Phe-Leu-(N-CH_3,O-CH_3)Tyr-Val-OMe (5). The methyl ester group of the linear hexapeptide was replaced by p-nitrophenyl ester, the Boc- group was removed and finally cyclisation was carried out by active ester high dilution technique to get the cyclic hexapeptide N-methylated Dichotomin-A. A similar cyclic peptide was synthesised by replacing L-valine by D-valine. The compounds were characterised by ^{1}H NMR, IR, FABMass and elemental analysis.

The synthesised compounds were evaluated for antibacterial and antifungal activities and were found to possess potent antibacterial activity and considerable antifungal activity as compared to the standard drugs.

B5 Active site characterization of human Catechol O-methyltransferase

U.D. Deshpande[2], S.S. Deshpande*[1], A.T. Sangamwar3, S.S. Pekamwar[3] and R.S. Gaud[4]

1. S.N. Institute of Pharmacy, Pusad 445 204, India.
2. School of life sciences, SRTM University Nanded 431 606, India
3. Nanded Pharmacy College, Shyam Nagar, Nanded 431 605, India
4. Advisor - I, AICTE New Delhi

Adminstration of L-Dopa along with peripheral dopa decarboxylase inhibitor (DDC) is the standard therapy in treating parkinsonism. DDC inhibits decarboxylation of L-Dopa in peripheral issues, however, another enzyme catechol O-methyltransferase (COMT) degrades L-Dopa in peripheral issues into 3-methoxytyrosine. Hence inhibition of COMT is considered as adjune therapy in Parkinson's treatment.

The rat COMT crystallographic structure has been resolved and hence the present study aims to homology model the human COMT using rat COMT as a template.

The human COMT homology model exhibited similar structure with highly conserved active site except two changes that Val 173 and Met 201 in rat COMT are replaced by Trp 173 and Arg 201 in human COMT.

The docking studies performed on human COMT revealed that the nitrocatechol compounds may serve as better inhibitor.

The pharmacophore measures and skeleton structure has been used to analyse the existing chemical databases. The QSAR and QSPR studies have been performed on the analogues obtained from the chemical databases.

Currently virtual combinatorial libraries are being generated to develop throughput docking and screening methodologies.

B6 Synthesis & Pharmacological Screening of 2 [(N-substituted phenyl) aminomethyl]-3- [(N,N-dialklylamino) alkyl] 7 halo-3,4 dihydro – 4 (3H) quinazolinones as possible H1-antihistaminic agents

M.B.Raju, Dr.S.M. Shantakumar, G.Amarnath, Nisha Sangra*

V.L.College of pharmacy, Raichur 584 103, Karnataka

In an effort to synthesize potent histamine H1 receptor antagonist, we have synthesized eight new

quinazolinone derivatives, designed on the basis of triangular Pharmacophoric requirement of Histamine H1 receptor antagonism.

Halogenated Anthranilic acid (I) were reacted with Chloroacetylchloride and the products were cyclised with acetic anhydride to give the corresponding Benzoxizanones(II). These were treated with 3[N,N-diethylamino] propyl-1-amine to get 2-chloromethyl-3[3'-(N,N-dimethylamino)propyl] 6-halo-3,4-dihydro quinazoline –4-3(H) ones (IIIa-h) which were reacted with p-substituted phenyl amines to get the title compounds.

The compounds synthesized were characterized on the basis of elemental analysis, IR 1HNMR and Mass spectral data. The compounds were screened in vitro for H1 antihistaminic activity by guinea pig ileum method and in vivo by Histamine chamber method. All the compounds displayed H_1antihistaminic activity.

B7 Novel synthesis and anticancer activity of substituted Thiazolyl & Benzothiazolyl Quinazolones

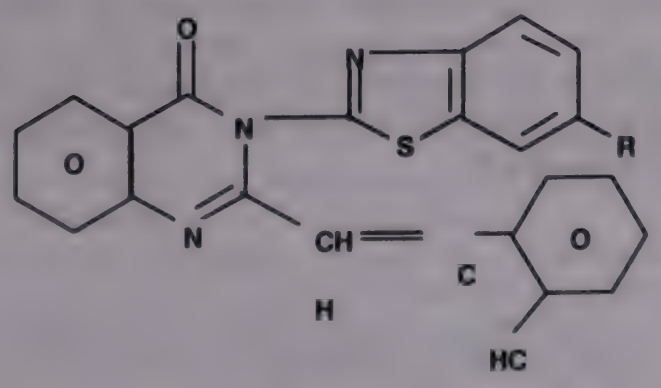
***[1]D. Patra, [2]D. Bhatta, [3]Pratap K. Sahu**
[1]R. P. Swain

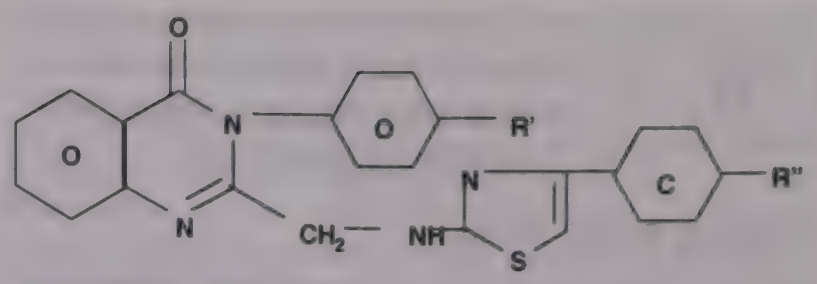
1. University Department of Pharmaceutical Sciences, Utkal University, Bhubaneswar, Orissa
2. Dept. of Chemistry, Utkal University
3. Jaydev College of Pharmacy Naharkanta, Orissa.

Heterocyclic compounds having "Quinazolone" nucleus with bridged 'N' atom possess many biological activities such as antitumor, antioxidant antimicrobial and antiviral properties.

It has been reported that compounds having substituted thiazole/benzothiazole nuclei with the molecular structure of quinazolones exhibit prominent anticancer activity.

Hence, we have been encouraged to design and sysnthesize compounds like 2-Aryleden – 3 - (2'-Substituted benzothiazoly) quinazolinones and 3-substituted phenyl – 2 - (4-substituted benzyl -2'-thiazolyl aminomethyl) quinazolinones.





Synthesized by incorporting thiazole, 2-substituted benzoxazinones and schiffs base linkages, and the compunds were charctersied by spectral and elemental analyses. The compounds were screened at 5 different concentrations in a battery of about 60 human tumour cell lines arranged in nine sub panels, representing diverse histologies at National Cancer Institute, Bethesda, USA, according to recent protocol. The values for response parameters TGI, GI_{50}, LC_{50}, were calculated statistically and two compounds out of five exhibited significant anticancer activity against CCRF-CEM, MOLT-4, RPMI-8276, K-562 of leukemia and HOP-92 of non-small cell lungs cancer.

B8 Synthesis and pharmacological evalvation of new 10-Arylidene derivatives of 4 phenyl-2,4,5,6,7,8-hexahydro Quinazolon[2,3-b] Thyzolidin-9-0ne"

B. Jayalakshmi, B. Shivkumar & V.M. Reddy
Ch. Ravishankar Memorial Medicinal Chemistry Research Laboratory University College of Pharmaceutical Sciences, Kakatiya University, Warangal 560 009

4-Phenyl 3,4,5,6,7,8-hexahydro qunazolin-2-thiene has been obtained from the condensation of 2-benzyliden-cyclo-hexanone with thiourea and reacted with ethyl chloroacetate in acetone over anhydrous potassium carbonate. It yielded a mixture of two cyclized isomeric products. Probably one involving N-H and the other involving N^3-H. The major product being insoluble in methanol could be separated effectively. That compound has been characterized as 4-phenyl-3,4,5,6,7,8-hexahydroqunazolin[1,2-b] thiozolidin-9-one and a plausible mechanism has been postulated. It has then been condensed with five different aromatic aldehydes to obtain the corresponding arylidene derivatives. All of them have been characterized by their analytical and spectral data.

The new arylidene derivatives have been evaluated pharmacologically for their analgesic and anti-inflammatory properties. Two of the new compounds have been found to possess good analgesic and anti-inflammatory activity.

B_9 Eco-friendly synthesis of some new Hexa substituted 1,4-Dihydropyridines

T. Suresh & V.M. Reddy*

Ch. Ravishankar Memorial Medicinal Chemistry Research Laboratory.

University College of Pharmaceutical Sciences, Kakatiya University, Warangal 506 009. (A.P.) India

In view of ever-growing pharmacological importance of 1,4-dihydropyridines and difficulties encountered in their synthesis, a more facile micro-wave irradiation method has been studied in the present investigation. As many as twelve new 1,2,3,4,5,6-hexa-substituted 1,4-dihydropyridines have been synthesized, purified and characterized with the help of their analytical and spectral (IR, PMR & MASS) data. The synthesis has been effected making use of ethyl acetoacetate appropriate aromatic aldehyde and appropriate primary amine by the modified Hantzsch method. Present syntheses have been carried out under two different experimental conditions: Conventional and MW irradiation. It could be observed, uniformly, without any exception that the yields of the products are high and the reaction time being reduced, drastically in the MW irradiation method. The compounds have been characterized based on their elemental analysis and spectal (IR, PMR & MASS) data. The pharmacological screening of the compounds for the calcium channel blocking action-using Nifedipine as the standard showed them to be insignificant. It may be due to the presence of an N-substitutent.

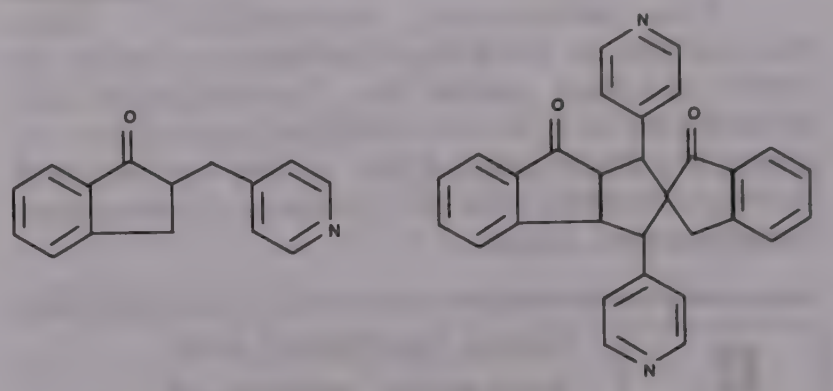
B_{10} Formation, characterization and study of a dimer of 2-(4-pyridylmethyl)-1-indanone as a novel non-steroidal aromatase inhibitor

Dharam Paul Jindal[1], Birinder Jit[1], Gaurav Narang[1]*, Ranju Gupta[1], R.W. Hartmann[2] and Anja Palusczak[2]

1. University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh-160 014.
2. Fachrichtung 8.5, Pharmazeutische Chemie, Universitat, Des Saarlands, Postfach 151150, D-66041, Saarbrücken, Germany.

In recent times, aromatase inhibitors have found a great significance for the treatment of postmenopausal breast cancer. A number of steroidal and non-steroidal aromatase inhibitors have been discovered and a plethora of them are in various stages of clinical trials. The main issue concerning the selectivity of aromatase inhibitors for cytochrome P_{450} aromatase, still needs to be addressed completely. Recently 2-(4-pyridylmethyl)-1-indanone (1) and some of its derivatives have been reported as more selective and potent non-steroidal aromatase inhibitors as compared to aminoglutethimide.

A number of modifications of this group of non-steroidal aromatase inhibitors have been carried out in order to obtain even stronger and selective inhibitors of estrogen biosynthesis. In a similar attempt, a number of indanone derivatives have been synthesized in our laboratory. During the course of investigations, we came across the formation of a dimeric (2) form of 4-pyridylmethyl-1-indanone from Aldol condensation of indanone with pyridine-4-carboxaldehyde in alkaline conditions.



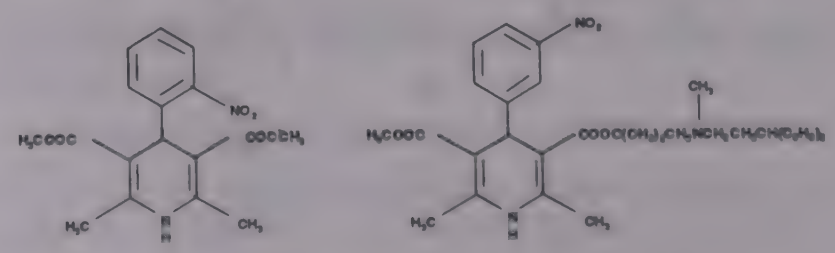
The structure of the dimer 2 was elucidated with the help of various spectral techniques and elemental analysis and has been screened for its aromatase inhibitory activity using human placental microsomes and [1ß, 2ß-^{3}H] testosterone at University of Saarland, Germany. The relative potency of this compound was found to be three times as compared to aminoglutethimide. This type of compounds might hold a good potential for development of aromatase inhibitors with a better therapeutic profile and may be exploited further.

B_{11} Synthesis of some 1,4-dihydropyridine type calcium channel blockers

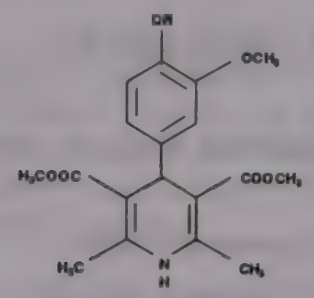
Dharam Paul Jindal, Gaurav Narang, Priyanka Jain* and Ranju Gupta

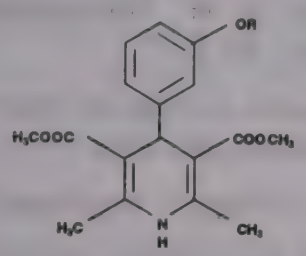
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh 160 014

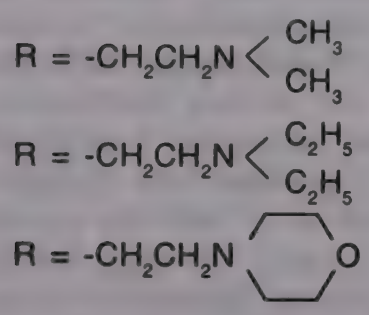
Cardiovascular ailments pose a staggering economic burden on society. To overcome this, a large number of structurally dissimilar biologically active nuclei have been discovered. Among them calcium channel blockers have become one of the major advances for the treatment of cardiovascular disorders. Among the various classes, dihydropyridines as exemplified by nifedipine (1) and lecarnidipine (2) attract prime interest due to their high potency and lesser side effects.

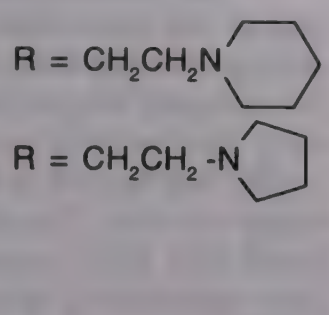


In the present study, efforts have been made to develop the hybrid structures having varied substitutions at phenyl ring. The parent 1,4-dihydropyridine nucleus has been prepared by condensation of aminocrotonate with aldehydes such as vanillin and 3-hydroxybenzaldehyde. Subsequent alkylation with hydrochlorides of various haloalkylamines gave the substituted dihydropyridines.









The structures of newly synthesized compounds were established by using various spectral techniques such as ultraviolet, infrared, proton NMR spectroscopy and elemental analysis. The evaluation of calcium channel blocking and vasodilatory activities of these compounds is in progress.

B12 Synthesis and anti-tumor activity of some Benzothiazole Selenolato metallic complexes

Meenakshi Gupta*, Amit Kumar Das

Krupanidhi College of Pharmacy, Koramangala, Bangalore 560 034

Nowadays, organoselenium complexes have attracted considerable current attention. Se-N intramolecular co-ordination have shown to play a vital role in the catalytic cycle of glutathione peroxidase, selenium containing anti-oxidant enzymes. Se has anti-oxidant and anti-carcinogenic potential. Se-N intramolecular co-ordination has also been extended to the synthesis of organo selenium complexes especially with group 12 metals. Some metal complexes with heterocyclic compounds have shown potent anti-tumor activity like Pt (IV), Ni (II), Pd (II), and Zn (II). So, attempts have been made to synthesize benzothiazole selenolato ligand of Zn(II),Cd(II),Hg(II) ,Cu(II),Ni(II) etc and screen them for anti-tumor activity. The experimental work done includes, first, lithation of benzothiazole ring at 2-position with n-butyl lithium at -78°C under N_2 atmosphere. Second, introduction of Se to lithated benzothiazole to get lithium benzothiazole selenolato ligand,and then it is followed by the formation of benzothiazole selenolato metallic complex with metal chloride like $ZnCl_2$, $CdCl_2$, $HgCl_2$, $NiCl_2$,$CuCl_2$ .Various benzothiazole selenolato metallic complexes were synthesized $M[Se(BTA)]_2$ and were screened for anti–tumor activity using Ehlrich ascities carcinoma cell (EAC) induced albino mice. Out of these synthesized selenolato metallic complexes $Zn[Se(BTA)]_2$, $Ni[Se(BTA)]_2$ were found to be potent anti-tumor, since these compounds have shown increase in RBC, decrease in WBC , increase in life span ,decrease in ascitic fluid volume, increase in lymphocytes significantly. Different selenium complexes $M[Se(BTA)]_2$ where M=Zn,Cd,Hg,Ni,Cu were synthesized by the reaction of MCL_2 with lithium arene selenolato ligand of BTA $Se^+ Li^-$ and were characterized by different method like melting point ,thin layer chromatography ,infrared spectroscopy, nuclear magnetic resonance , mass spectroscopy ,atomic absorption spectroscopy . All these complexes were screened for anti-tumor activity. Out of these $Zn[Se(BTA)]_2$ was found to be potent , $Ni[Se(BTA)]_2$, $Cu[Se(BTA)]_2$ was moderately potent and $Cd[Se(BTA)]_2$, $Hg[Se(BTA)]_2$ were found to be inactive.

B13 Synthesis, Antimycobacterial Activity and QSAR Studies of Pyrazine Containing azetidine-ones

Bonde C. G* and Gaikwad N.J.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur 440033

The deterioration of human population due to the enhance prevalence of infectious diseases is becoming a worldwide problem. Over the last few years, tuberculosis is retrieving its place among these infectious diseases and today; nearly one-third of the world's population is infected with *Mycobacterium tuberculosis* with approximately three million patients deceasing every year. It is therefore essential to develop the new entities. Azetidine-2 ones are known to posses antibacterial, antifungal and antimycobacterial activities. Thus the present series was synthesized and evaluated against H_{37} Rv strain of M.Tuberculoses

Title compound was prepared by cycloaddtion of various Schiff's bases with chloracetyl chloride. The Schiff's bases were prepared from the hydrazide of ethyl ester of 2-methoxy pyrazine and substituted benzaldehydes. All the synthesized compounds were characterized by elemental analysis, IR, NMR and Mass spectroscopy. Anti-mycobacterial testing was carried out by tube dilution technique. QSAR studies were carried out using 19 different descriptors by Cache Worksystem Pro 5.0 software.

Nineteen novel compound were prepared and screened for their antimycobacterial activity against H_{37} Rv strain of M. Tuberculosis. All nineteen compounds showed good antimycobacterial activity. Out of which one showed the antimycobacterial property to the compounds as r and r^2 is above 0.95, which is significant.

Potentiation of activity of schiff's base is a result of their conversion into azetidine-ones Pyrazine nucleus contain azetidine-ones was found to be active against M. tuberculosis. Molar refractivity and Log P is important to impart the antimycobacterial activity to the compound.

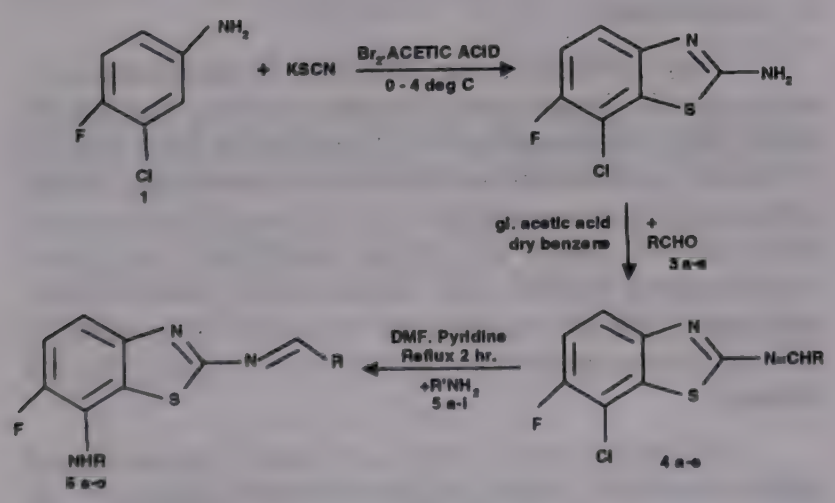
B14 Synthesis of 2-(substituted-benzylideneamino)-6-fluoro-7-(substituted-anilino)-benzothiazoles for antitumor activity

Ajay Gupta*, L.V.G. Nargund, Amit Kumar Das

Krupanidhi College of Pharmacy, Koramangala, Bangalore 560 034

3-Chloro-4-fluoro-aniline 1 was reacted with potassium-thiocyanate in the presence of glacial acetic acid to give 2-amino-7-chloro-6-fluorobenzothiazole 2. Bromine was used as cyclising agents in above reaction. Schiff's bases 4a-e of 2-amino-7-chloro-6-fluorobenzothiazole 2 & various substituted aromatic aldehydes 3a-e were prepared with the help of Dean stark apparatus using excess of dry benzene. Glacial acetic acid was used as a catalyst. Schiff's bases were substituted with various aromatic amines 5a-i by refluxing in the presence of dimethyl-formamide using catalytic amount of pyridine to get the title compounds 6a-o.

These compounds were screened for anti tumor activity using Ehrlich ascites carcinoma (EAC) induced mice. All compounds were administered daily for nine days starting 24 hrs after tumor implantation. Four animals from each group were sacrificed 24 hrs after the last dose and ascitic fluid volume, packed volume, hematological parameters were noted. Mean survival time (MST) for remaining four mice of each group was noted for 6 weeks. The assessment of drugs effect is done by counting Total Packed Cell Volume (TPCV) & survival time. 6 derivatives were found to possess moderate activity and 4 derivatives were found to be potent among the 15 derivatives screened.



R=C_6H_5, 4-$OCH_3C_6H_4$, 4-OH-C_6H_4
4-OH-3-OMe-C_6H_4, 4-N$(CH_3)2C_6H_4$

R'=C_6H_5, 4-$OCH_3C_6H_4$, 2-$OCH_3C_6H_4$
4-OH-C_6H_4, 4-NO_2-C_6H_4 etc

B15 Synthesis and pharmacological evaluation of doxurubicin-water soluble polymer drug conjugates targeted to estrogen receptor drug delivery

Asaraf Ali M*, Manogaran E., Rajagopla K. Sadath Ali L.

Sanjivani College of Pharmaceutical Science, Rajota, Rajasthan 333 503

K.K. College of Pharmacy, Chennai 600 093

The anthracycline antitumor drug, doxrubicin, is one of the most effective chemotherapeutic agents employed in the treatment of breast cancer. Although the cytotoxic mechanism is not entirely understood. Here Synthesis of di-peptide, equimolar amount of glycine and leucine di-Peptide synthesis than dipeptide linked with Poly L-malic acidl(PMLA) than this spacer linked with drug doxrubicin prodrug. pro-drug design often represents a specific chemical approach to mask the undesirable drug properties such as limited bioavailability. On the other hand targeted pro-drug design represents a new strategy for directed and efficient drug delivery, particularly targeting the pro-drug to a specific enzyme or specific membrane transporter, both has a potential and a selective drug delivery system in cancer treatment. Estrogen receptor binding and in vitro growth inhibition of breast cancer cells as a function of estrogen receptor and multidrug resistance expression. The targeting the pro-drug, which conjugated with water soluble polymer, has a site specific targeted weapon in the particular tumor cells due to its synergistic effect of increased vascular permeability and decreased the tissue drainage.

B16 Synthesis of 4,4¹(imino-hex-4-oxo-2,5 dienyl)-6-(4-hydroxy anisole)-diphenyl sulfone and screening of its cyclo-oxygenase II inhibitory and anti-inflammatory activities

Madhu. C. Divakar

College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore - 44. Tamil Nadu

4,4¹-(Imino-Hex-4-oxo-2,5 Dienyl)-6-(4-Hydroxy Anisole) - Diphenyl Sulfone was synthesized from dehydrozingerone and dapsone. Dapsone is one of the drugs of choice for leprosy, but its increased level of toxicity renders itself less prescribed for long-term uses with high doses. The results obtained showed that the Schiff base formed (DZDAP) had got less toxicity as compared to the parent compound dapsone; as

indicated by the LD_{50} values. The new compound DZDAP again showed considerable anti-inflammatory activity in carrageenan induced paw oedema and effective cyclo oxygenase II inhibitory activity.

Long-term administration of dapsone is not suggested in leprotic patients because of its high level of toxicity. Patients with the complication of erythema nodosum leprosum are usually advised to take anti-inflammatory activity. Dehydrozingerone is another minor compound present in ginger roots and rhizomes, reported to have effective anti-inflammatory activity. In our present work, we prepared a Schiff base by coupling dapsone and dehydrozingerone and screened its toxicity; anti-inflammatory and cyclo oxygenase II inhibitory activities.

DZDAP showed significant inhibition of cyclo oxygenase II enzyme activity and careegeenan induced paw oedema as compared to dehydrozingerone and dapsone. DZDAP showed 65.06% inhibition of paw oedema while dapsone and dehydrogingerone produced 34.8% and 59.85% inhibition respectively in the anti inflammatory activity studies. Acute toxicity studies for evaluating the LD_{50} of DZDAP showed a value of 532.1 mg/kg, which is higher compared to the LD_{50} value of dapsone (237.1373 mg/kg). It is already reported that cancerous cells are rich in cyclo-oxygenase II enzyme. Therefore an agent reduces the cyclooxygenase II enzyme levels in the cells can be effectively used as a good antiinflammatory and anticancer agent in therapies.

B_{17} Synthesis and biological activities of new 6-bromo 4 (3H) - quinazolinon-3-YL 1,3,4-oxadiazoles, thiadiazoles & triazoles

T.M. Kulanthavel, Navanath Kalyane & V.M. Reddy

Ch. Ravishankar Memorial Medicinal Chemistry Research Laboratory, University College of Pharmaceutical Sciences, Kakatiya University, Warangal 506 009.

σ-Bromo-2-methylbenzoxozinone obtained from condensation of 5-bromoanthranilic acid with acetic anhydride has been reacted with ethyl glycinate to get ethyl (σ-bromo-2-methyl-4-quinazoline-3-yl) acetate. Which has been converted into its acid hydrazide by the reaction with hydrazine hydrate. The acid hydrazide has been used as a synthon to build up three different 5-membered heterocyclic systems over the quinazolinone system. First it has been reacted with carbon disulphide in alcoholic potassium hydroxide to get the 1,3,4-oxazolidin-2-thiene on acidification with acetic acid the intermediate potassium salt of acetyl dithicarbozinate on hydrazinolysis yielded the corresponding triazolidin-5-thione. Whereas the acid hydrazide could be converted into its acetyl-phenylthiosemicarbazide on reaction with phenyl isothicynate. The thiosemicarbazide on treatment with concentrated sulfuric acid could yield the respective 1,3,4-thiadiazole. The same on the other hand, could yield 1,3,4-triazol-2-thiol on reaction with sodium hydroxide.

All the intermediate and final compounds have been characterized on the basis of their analytical and spectral (IR.PMR and mass) data.

The new quinazolinonl oxadiazoles, thiadiazoles and triazoles have been screened for their antibacterial, analgesic and anti-inflammatory properties by standard methods. Thiadiazole and triazolin-2-thiol have been found to exhibit good analgesic and anti-inflammatory activities.

B_{18} Synthesis and biological evaluation of some 2- aryl-4,5-disubstituted imidazoles

S.K. Mishra[1], S.K. Sahu[1], S.P. Pattanayak[1]*, D.M. Kar[1], B.C. Guru[1] and C.S. Panda[2]

1. University Department of Pharmaceutical Sciences, Utkal University, Vani Vihar, Bhubaneswar-751004
2. P.G.Department of Chemistry, Berhampur University, Berhampur 760 007, Orissa.

Compounds carrying imidazole nucleus are reputed to elicit activities such as antibacterial, antifungal, anthelmintic, antispasmodic, antileukaemic etc. In view of this, the title compounds were synthesized and screened for their possible anti-inflammatory and in vitro antibacterial activity.

A solution of diketone, ammonium acetate and hot glacial acetic acid was treated with appropriate aldehyde in glacial acetic acid. The mixture was kept under reflux for 1h, cooled and diluted with water. Neutralization with liquor ammonia afforded the crude imidazole, which was filtered, dried and recrystalized from ethanol. A series of title compounds (2a–d) were synthesized by condensation of benzil (1), with substituted aryl aldehydes [Benzaldehyde (a), p-nitrobenzaldehyde (b), furfural(c) and p-dimethyl aminobenzaldehyde (d)] and another series (4a-d) by condensation of isatin (3) with the same series of substituted aryl aldehydes(a-d).The purity of the synthesized compounds was judged by their C,H and N analyses and the structure was established on the basis of IR and NMR spectral data.

The compounds (2a–d,4a–d) were screened for their anti-inflammatory activity by carrageenan induced rat hind paw oedema method. All the test compounds showed anti-inflammatory activity with different percentage of protection at the end of 3hrs.The compounds (4a –d) resistered good protection than compounds (2a –d). The maximum anti-inflammatory activity (% protection) was observed by compound 4b(51.72), which is comparable with standard, Diclofenac sodium (55.17).

The compounds were also screened for antibacterial activity by agar diffusion method with 24hrs old cultures of *Actinomycus pyoginus* and *Klebsiella aeruginosa*. The test results showed good

inhibitory activity for almost all the compounds, but none showed better or comparable activity to Ampicillin trihydrate (Std.).

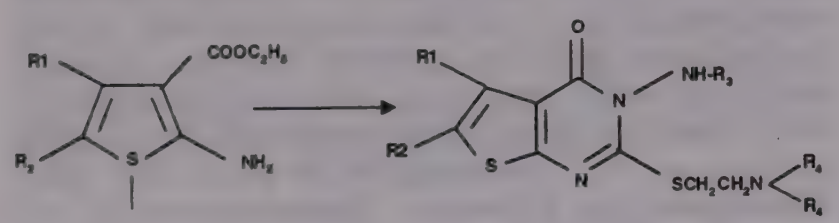
From the test results, it is very difficult to conclude any thing at this stage, unless detailed toxicity studies are carried out to prove them as safer drugs.

B_{19} Design, synthesis and H_1-antihistaminic activity of novel theino [2,3-*d*] pyrimidinones

B. Shireesha*, K. Umashankar, Visalakshi Chivukula and A. Raghu Ram Rao

+Medicinal Chemistry Research Division, University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, AP, India

In recent years different fused pyrimidinones were reported from our laboratory as potentially useful antihistaminics and bronchodilatory agents. In continuation of our work an attempt has been made to design new H_1-antihistaminic compounds using CS Chem. Office/Chem.3D ultra by drawing triangular pharmacophoric model. Based on these results a novel series of 2,3,5,6-substituted thienopyrimidin-4-ones (V) were synthesized using appropriately substituted 2-amino thiophene-3-carboxylic esters as synthetic precursors. The final compounds (V) were evaluated for antihistaminic activity. The pA_2 values for the compounds *(in vitro)* indicated potent activity and they were found to be comparable with the standard drug chlorpheniramine maleate.



R_1 = -CH_3 R_3 = H_1NH_2
R_2 = -CH_3 R_4 = -CH_3
R_1R_2 = -$(CH_2)_4$

B_{20} Synthesis and anti-inflammatory activity of isatin and isatin derivatives

D.M. Kar[1], S.P. Pattanayak*[1], A.J.P. Choudhury[1], M.Banarjee[1], S.K. Sahu[1].

1. University Department of Pharmaceutical Sciences, Utkal Univeristy, Vani Vihar, Bhubaneswar 751 004.

Isatin is an endogenous compound identified in human and rat tissues. Isatin derivatives are reported to elicit promising pharmacodynamic activities viz. Antimicrobial, antidepressant, anti-inflammatory, analgesic etc. In view of these findings we have attempted to incorporate isatin and some isatin derivatives along with their mannich bases for anti-inflammatory screening.

Reaction of Isatin (1) with thiosemicarbazide gave monothiosemicarbazone (2). Acetylation of 2 with acetic anhydride furnished the corresponding N-acetylated D^2-1, 3, 4- thia diazoline derivative (3). The N-Mannich bases 4 & 5 (from 2, 3 respectively) were prepared by condensing with formaidehyde and secondary amine i.e. morpholine and diethylamine respectively. The structure of all the new compounds were confirmed by their elemental analyses and IR spectral data.

The compounds (1-5) were screened for their anti-inflammatory activity by carrageenan induced rat hind-paw oedema method. All the test compounds showed significant activity ($p<0.05$) upto 3 hr. However 2 showed max. protection (70.3%) followed by 3 (52), 4(60.81), 5(41.89).

This may suggest that less substitution (Thiosemicarbazide) in isatin increases the anti-inflammatory potential. Hence, it is reclusive to approach isatin with multiple substitutents (as spiro or mannich bases) towards anti-inflammatory activity.

B_{21} Synthesis and biological evaluation of glycolamide ester of cinmetacin (a prodrug)

Anju Goyal* and S.C. Chaturvedi

*B.N. College of Pharmacy, Udaipur (Raj.), 313001
VDeptt. of Pharmacy, G.S.I.T.S, Indore

The present investigation is aimed to minimize the side effects while maintaining the analgesic, anti-inflammatory activities, therefore glycolamide ester of cinmetacin with diethylamine was synthesized and was then screened for biological activities i.e. analgesic, anti-inflammatory and ulcerogenic. Cinmetacin (1-cinnamoyl-5-methoxy-2-methyl indole-3-acetic acid) is derived from indomethacine and is used as an analgesic and anti-inflammatory agent. The major side effect of this drug is gastric ulceration.

The glycolamide ester was prepared by reacting cinmetacin with disubstituted 2- chloroacetamide of diethylamine, which in turn was prepared by reacting diethylamine with 2-chloroacetylchloride. The compound so obtained was purified, recrystallized and then characterized by TLC, M.P., IR, NMR and mass spectra. The glycolamide ester of cinmetacin was amorphous and insoluble in water therefore all biological testing was carried out as homogenized suspension in 2% w/v gum acacia. Albino rats were used for experiments. Anti-inflammatory activity was carried out by the procedure reported by Winter et al. Analgesic activity was performed by Tail flick method using Techno-analgesiometer. The ulcerogenic activity was carried out by the method reported by Cioli et al.

It was found that the synthesized glycolamide ester exhibited analgesic and anti-inflammatory activity comparable with cinmetacin. The major side effect i.e. gastric ulceration was found to reduce markedly. This indicates that probably blocking of free carboxylic group has reduced the ulcerogenic activity.

However, further studies (toxicity, LD_{50}) should be carried out to ascertain the usefulness of these compounds as superior analgesic and anti-inflammatory agent than the presently available one.

B_{22} Design and synthesis of N N'-Bis-[2-(N-phthalimido) acetyl / benzoyl / ethyl] ethylene diamine / alkylamines as possible bis-DNA intercalators

Sunil V. Sharma, Santosh H. Dongre*, Shanmugharajan Shrishailappa Badami, Vijayan P and Suresh B.

Department of Pharma. Chemistry, JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

DNA intercalators represent the most widely used class of anticancer drugs. Dimerization of intercalating moieties can lead to increase in the DNA binding affinity. Such bis-intercalation causes more pronounced structural changes of DNA. Hence, in present investigation we have designed and synthesized a novel series of dimeric compounds containing phthalimide nucleus as possible bis-intercalator. Nine compounds N,N'-bis-[2-N-phthalimido) acetyl/benzoly/ethyl] ethylene diamine/alkyl amines were synthesized and characterised. *In vitro* antitumor activity was screened by four different models i.e. wheat rootlet growth inhibitory studies, antimitotic studies using onion root tip model, short term cytotoxicity against DLA cells and cytotoxicity against HEP_2 and Vero cell cultures. Similarly, DNA fragmentation was studied using Agarose get electrophoresis method.

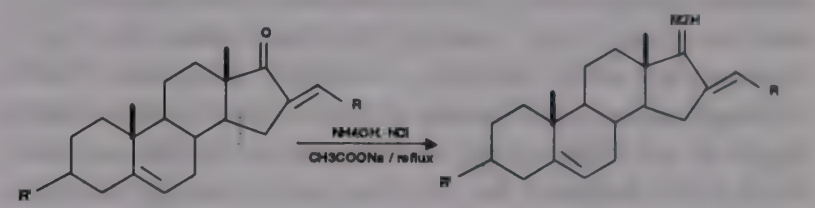
In general, all compounds showed similar activities with about 50% growth inhibition at 100µg/ml concentration in wheat rootlet inhibition assay. These compounds showed more than 50% inhibition of mitosis at 50µg/ml concentration in onion root tip model. Three compounds containing ethylamine liner chain were most cytotoxic against DLA cells with more than 50% cytotoxicity at a concentration below 100µg/ml. In the cell culture study, three compounds (I, III and IV) tested showed higher activity against the cancerous cells (HEP_2) than the normal cells (Vero). The CTC_{50} values were in a range of 90-165µg/ml against HEP_2, while it was ranging between 153-258µg/ml against Vero cells by both MTT and SRB methods. Two of the compounds showed appreciable fragmentation of DNA on electrophoretic plate, thus proving the possible intercalation. This study forms a platform to identify newer bis-intercalating agents.

B_{23} Synthesis and biological evaluation of some steroidal oximes as antine oplastic agents

Sonal Dubey*, Dharam Paul Jindal and Poonam Piplani

University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh 160 014, INDIA

The role of steroidal inhibitors has long been established in the treatment of many types of cancer, particularly breast cancer and benign prostatic hyperplasia , biosynthesis of androgen and estrogen being the key modulators in these diseases.The inhibition of enzymes involved in the biosynthesis of estrogen and testosterone have proved to be helpful in the treatment of breast and prostate cancer respectively. Certain 16-substituted steroidal oximes have been synthesized with this aim. Dehydroepiandrosterone was used as the starting material, and was condensed with various aldehydes (eg.pyridine-2-carboxaldehyde, pyridine-3-carboxaldehyde, 4-(dimethylaminoethoxy)-3-methoxybenz-aldehyde etc.) using aldol condensation. Further modifications and oxime formation were done to synthesize 16-substituted-17-oximino-androst-5-ene



derivatives. The structures of newly synthesized steroidal derivatives were determined with the help of spectral and elemental analysis. All the compounds were tested for their antineoplastic activity in vitro against 3-cell line (Breast, CNS and Brain) at NCI, Bethesda,USA. Some of the compounds tested have been found to be active in this assay. All the active compounds have been sent for further detail testing for anticancer activity at NCI using 60-cell line bioassay over a 5-log dose range.

B_{24} A new, mild and efficient method for conversion of aryl benzyl ethers to aryl acetates: application in solution and solid phase combinatorial library synthesis

Asit K. Chakraborti, Sunay V. Chankeshwara* and Gurmeet Kaur

Department of Medicinal Chemistry, National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, S. A. S. Nagar, Punjab 160 062, India.

Combinatorial chemistry has been recognized as one of the most powerful tools for discovery of pharmaceutically interesting compounds. Since the original Nobel Prize winning idea of solid phase peptide synthesis, Merrifield resin has been used for more than 20 years for the production of a range of small molecules. The use of Merrifield resin for combinatorial synthesis of small molecules increased dramatically the diversity and number of small molecules available for medical and biological applications such as ACE inhibitors, antifungals, anti-inflammatory, antitubercular, HIV protease inhibitors and many more.

Following the synthesis, an important early step in the characterization of the compound is to obtain it in adequate concentration in solution to perform an accurate pharmacological activity measurement (potency). For the characterization in the solid phase organic synthesis two methodologies are used: (i) conventional liquid phase techniques in which cleavage of the compound from the solid support is performed and (ii) non-destructive techniques for samples bound to the solid phase. The indirect information derived from the compound obtained after cleavage is used to judge the intended chemistry carried out on the solid support.

The newly introduced "on-bead" methods of characterization of combinatorial libraries require sophisticated and costly technologies like FTIR microscopy, ATR, MALDI, HR-NMR, and MAS-NMR. Although these techniques provide satisfactory results there is ultimate need of separation of the product from solid support for further biological evaluation. Thus, the need of a mild cleavage protocol for getting the product from solid support without any loss of the original identity of the molecule and purity of the products is in high demand.

Under the present investigation we have developed a new and mild protocol for cleavage of various phenolic derivatives from the solid support. Further, the methodology enables us to regenerate the solid supports for reuse in combinatorial reactions.

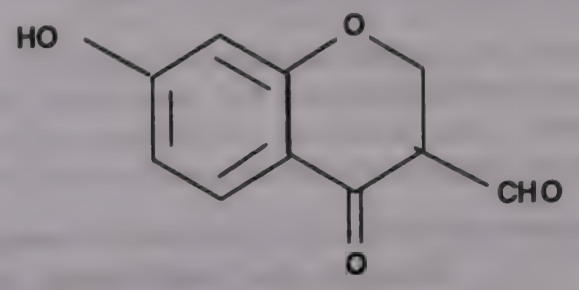
B25

7-hydroxy or aryloxy substituted 3-formylchrom-4-one scaffolds through solid phase synthesis

Madhavi Sisodia[1], A.K. Shrivastava[2]*, Sanjay Batra[3], S.K. Jain[1], R.K. Agrawal[1]

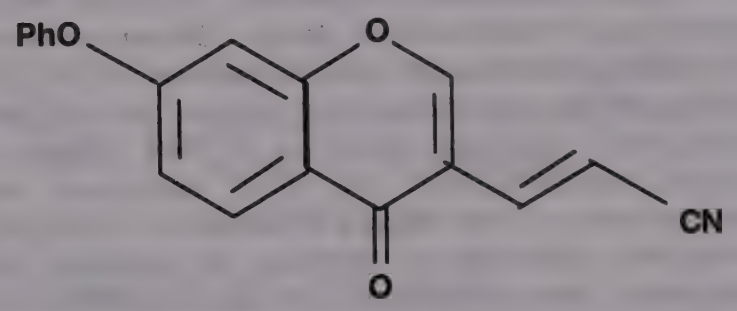
1. Department of Pharm. Science
   Dr. H.S.G. Vishawavidyalaya, Sagar
2. Medicinal Chemistry Division, C.D.R.I. Lucknow (UP)
3. B.N. College of Pharmacy, Udaipur

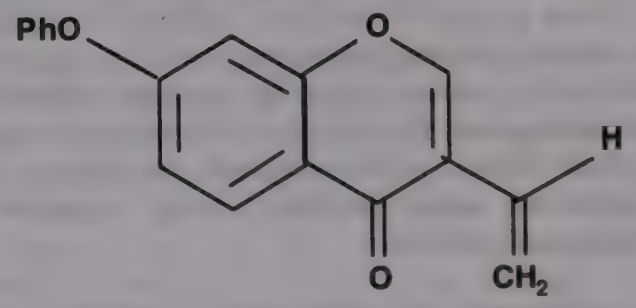
3-Formylchrom-4-ones are novel synthetons, which can generate wide variety of heterocyclic systems. Synthetic utilization of these scaffolds are mainly due to three electron deficient carbons (C# 2, 3 & 4) which enables them to serve as Michael acceptor, heterodiene as well as ideal dienophiles to generate fused heterocycles some of such derivatives have already been displayed potent antihistaminic activity.

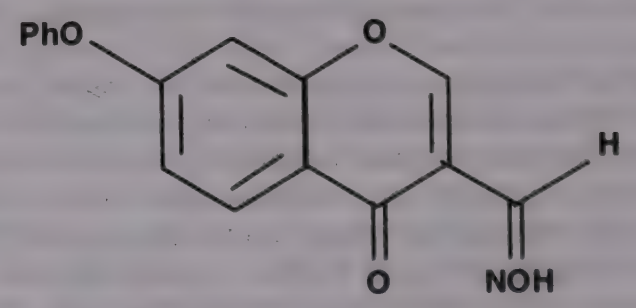


7-Hydroxy-3-formylchrom-4-one

Syntheses of these 7-Hydroxy-3-formylchrom-4-ones were first attempted using organic solvents such as Diisopropylethylamime (DIEA), Dimethylaminopyridine (DMAP), Dimethylformamide (DMF) etc. Two typical methods were tried using protected and unprotected 7-hydroxy group. It was found that unprotected hydroxy group yields resinous mass hence only one strategy of using protected hydroxy group was found successful. This synthetic strategy was further translated into solid support using 2-Chlorotrityl resin.







As the result three scaffolds namely 7-benzyloxy-3-vinyl-chromen-4-0ne (I), 3-(7-benzyloxy-4-oxo-4H-chromen-3-yl)-acrylonitrile (II) & 3-(7-benzyloxy-4-oxo-4H-chromen-3-yl)-acryloxime (III) in accomplishing said syntheses 4 intermediates were synthesized. 13 C NMR, FTIR, FABMS, PMRS and SBFTIR were used along with conventional methods to characterize these new scaffolds and intermediates.

B26 Synthesis, qsar modelling and hypoglycemic activity of thiazolidine derivatives

Prashanth kumar B.R*, S.M. Hipparagi, B.G. Desai, V.C. Yeligar

K.L.E College of Pharmacy, Bangalore-10.

M.D.Karvekar, Govt. College of Pharmacy, Bangalore

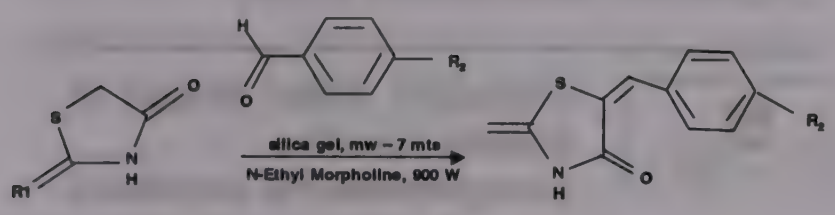
B.R.Srinivasa, Scientist, Astra Zeneca India, Bangalore

Lakshmi adhikary, Scientist, Biocon India , Bangalore

R.Raghu,Tata Elexsci, Bangalore

Venkatesh, R.Kore,Satish.N.K,Ragavendra,Pranesh Guddur.

I. Synthesis:
With an attempt for Accelerated drug discovery we have synthesized substituted thiazolidine 2,4 diones(11 compounds) and substituted thiazolidine 2-thio,4-ones (11 compounds) by knoevenagel condensation.

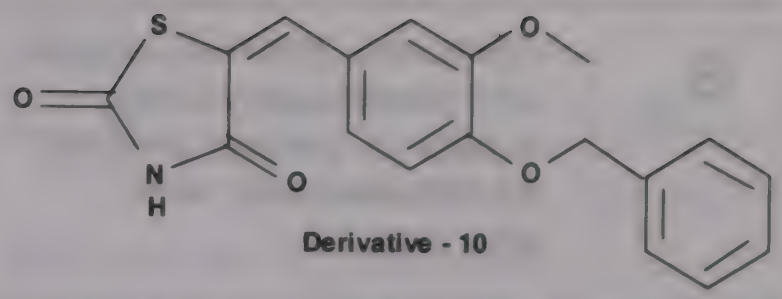


R1 - O = Thiazolidine 2, 4-dione
R1 - S = Thiazolidine 2 - thio, 4-one

Above reactions are carried out using microwave irradiation technique, which was found to be environmentally benign and rapid.

II. QSAR Studies:
In order to bring down the number of compounds for pharmacological screening, the synthesized compounds were subjected to QSAR studies to predict the hypoglycemic activity using MOE software. The structure of compounds which are known to have hypoglycemic activity from the journal are energy minimized, applied 2D and 3D molecular descriptors followed by PLS analysis and cross validated and the test compounds were predicted for hypoglycemic activity, top 14 compounds out of 22 predicted to be active are taken for pharmacological evaluation.

II. Pharmacological evaluation:
Pharmacological evaluation was done by glucocorticoid induced peripheral insulin resistance by using male Sprague dawley rats Weighing 240-280 gms, 4 animals / group for 9 days. Differences between control (Dexamethasone treated by S.C 10mg/kg body weight) and test compounds (Dexamethasone + test compound 10mg/kgbody weight by P.O route) are statistically evaluated by students t test (unpaired), out of 22 compounds candidate compound to be further investigated for both potency and toxicity is derivative-10.



Derivative - 10

B27 Microwave induced synthesis and angiogenesis inhibitory activity of some dimeric chalcones

Sunil V. Sharma, Gajinder Verma*, Prabodh Chander Sharma, Santosh Dongre, Shrishailappa Badami and Suresh B.

Department of Pharma. Chemistry, JSS College of Pharmacy, Ooty -643 001 (TN)

Chalcones are an important class of compounds possessing potent antioxidant, anticancer activity. Certain chalcones exert their anitmitotic action by inhibition of tubuline polymerisation. In recent years, Angiogenesis inhibitors have immerged as a new class of anticancer agents. Hence, encouraged by the results of our earlier studies, we synthesized a new series of dimeric chalcones by modified Aldol condensation of an appropriate benzaldehyde or quinoline carbaldehyde with cyclohexanone in 2:1 mole ratio in alkaline conditions.

On the other hand, microwave induced organic reactions are gaining popularity for routine synthesis. It offers advantages like eco-friendly nature, highly accelerated reaction rate, economic and higher yields. It was observed that synthesis of dimeric chalcones required stirring of upto 4 hours. The yields were also poor. Therefore, in an eco-friendly approach, we performed the synthesis under microwave irradiation. All the reactions could be completed in less than two minutes while yields were significantly greater than the conventional method except for the reaction of 3-nitro benzaldehyde. All the dimeric chalcones used in this study exhibited moderate to high antiangiogenic activity. Two of the compounds showed very high inhibition of blood vessel formation at a concentration of 10mcg (antiangiogenic Index 4464.58 & 3554.50 respectively). These compounds consisted of 2-chloro quinoline nucleus. Thus, it could be inferred that presence of polynuclear heterocyclic ring favors the antiangiogenic activity. Similarly, activity of 3-nitro substituted compound was almost three fold more than the unsubstituted compound. This study forms a platform for developing newer anticancer agent acting by inhibiting angiogenesis.

B28 Synthesis, pharmacokinetic and pharmacodynamic profile of a novel prodrug of indomethacin with glucosamine

M.R. Bhojani, Deepika Nagpal and Suneela S. Dhaneshwar*

Department of Pharmaceutical Chemistry, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune 411 038.

Despite the enormous amount of research that has been carried out on the development of NSAIDs, their usefulness as clinical agents is still restricted by their gastrointestinal (GIT) side effects. Local GIT lesions produced by NSAIDs are attributed to direct contact mechanism resulting from local irritation produced by acidic group of the NSAIDs and local inhibition of prostaglandin synthesis in the GIT. The present work aims at masking free carboxylic group of indomethacin with equally effective antiarithritic drug glucosamine to produce mutual prodrug with reduced gastric side effects and better antiarithritic activity. Glucosamine conjugate of indomethacin was synthesized by modified Schotten-Baumann technique. Melting point, TLC, UV, IR, H-NMR as well as proton exchange NMR spectra supported the structure of the synthesized compound. In vitro hydrolysis of the prodrug in HCl buffer (pH 1.2) indicates that it is quite stable at the pH of stomach whereas in phosphate buffer (pH 7.4) it undergoes hydrolysis following first order kinetics, releasing free indomethacin and glucosamine, to give their biological actions. The prodrug at equimolar dose showed comparable antiinflammatory activity by Carrageenan induced rat paw edema method and better analgesic activity than indomethacin when screened by Writhing method. The prodrug was evaluated for antiarthritic activity by Freund's adjuvant induced arthritis. It showed better activity than the parent drug and slightly less activity than glucosamine. The prodrug was found to be profoundly less irritating to gastric mucosa as compared to indomethacin at ten times higher dose when screened for ulcerogenic activity by cold stress method of Rainsford.

B29 Synthesis and pharmacological evaluation of some new benzodiazepinyl benzofurans

S.M. Shantakumar, M.B. Raju, Y. SridharYadav, M.R. Shivanand*

V.L.College of Pharmacy, Raichur –584 103 , Karnataka

In an attempt to synthesize and evaluate new sedative and anticonvulsant activities, we have prepared ten new benzodiazepenyl benzofuran derivatives, and screened them for anticonvulsant activity. Since both benzofuran and benzodiazepine have sedative, CNS depressant and anticonvulsant activities, the title compounds may be more therapeutically potent agents.

The key intermediate benzofuran-2-carboxhydrazide was prepared from salicilaldehyde. The hydrazide was reacted with ethylacetoacetate after diazotization to get compounds II_{a-j}. These are condensed with different aromatic aldehydes in presence of 5% NaoH to get the corresponding derivatives III_{a-j}. These were converted to the compounds IV_{a-j} by condensing with o-Phenylenediamine.

The title compounds were assigned structure based on the elemental analysis IR, ^{1}H-NMR, and Mass spectral data. The compounds were tested for anticonvulsant activity on albino rats by standard pharmacological procedures. All the test compounds displayed significant anticonvulsant activity when compared with phenobarbitone sodium.

B30 Computer aided design of protein tyrosine phosphatase-1B inhibitors as anti-diabetic agents

Mohamed Diwan Mohideen.K.A.*, N.Ravi Prakash Reddy, A.Jagan Mohan Rao, A.Ramakrishna, D.Sagar, G.Ram Babu.

'BioCampus', Gvk Bio Sciences Pvt. Ltd., Begumpet, Hyderabad

Protein Tyrosine Phospahtase 1B plays a role in the negative regulation of insulin signaling and is involved in the insulin resistance associated with Type 2 Diabetes. Since development of PTP-1B inhibitor could potentially ameliorate insulin resistance and normalize plasma glucose and insulin without producing hypoglycemia, it would be a major advance in the treatment of type 2 Diabetes mellitus.

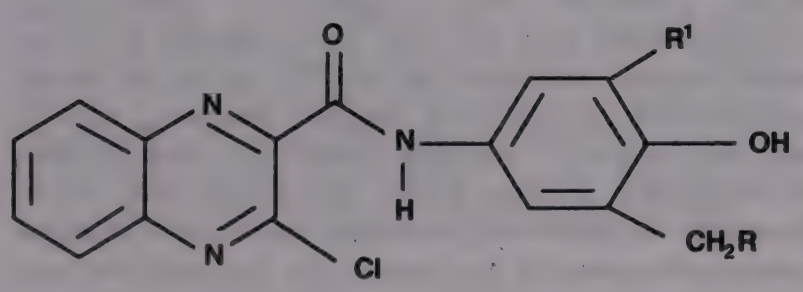
In our present study, 3D QSAR studies namely Molecular Field Analysis (MFA) and Receptor Surface Analysis (RSA) were done for the optimization of a newer series of 1,2-Naphthoquinone derivatives developed as PTP-1B inhibitors. The analysis was carried out on 45 analogues out of which 36 were considered as training set and rest as test set molecules. CH3 and H+ probes were used for model generation. Genetic Function algorithm (GFA) method was used. Model developed by MFA method has an r^2_{cv} (cross validated) of 0.821 while its r^2 (conventional) value is 0.88. For the RSA model r^2_{cv} and r^2 are 0.85 and 0.898 respectively. Both models indicate good internal and external predictive abilities. These models provide insight about the field descriptors for the design of potential inhibitors of PTP-1B.

B31 Microwave assisted synthesis of quinoxaline carboxamides as 5-hydroxytryptamine$_3$ (5-HT$_3$) antagonist for the treatment of cancer chemotherapy induced nausea and vomiting

Mahesh, R., Venkatesha Perumal, R,* & Vijaya Pandi, P.

Pharmacy Group, Birla Institute of Technology & Science, Pilani-333 031. Rajasthan.

Nausea and vomiting is a major side effect associated with cancer chemotherapy. Hence cancer chemotherapy is co-prescribed with 5-HT$_3$ antagonists to overcome such side effect. Very few selective 5-HT$_3$ antagonists are available and most of them exhibit varied side effects. We focus our research in developing newer chemical entities of specific 5-HT$_3$ antagonists. A series of novel Quinoxaline Carboxamides were designed according to the pharmacophoric requirement for the 5-HT$_3$ antagonist activity using Tripos Alchemy-2002. The designed compounds were synthesized using conventional and microwave heating. The synthesized compounds were characterized using spectral (IR, ^{1}H NMR, Mass) and elemental analysis data.



Where,
IIIa - R = dimethyl amine, R^1 = H
IIIb - R = diethyl amine, R^1 = H
IIIc - R = dibenzyl amine, R^1 = H
IIId - R = pyrrolidine, R^1 = H
IIIe - R = piperidine, R^1 = H
IIIf - R = morpholine, R^1 = H
IIIg - R = methyl piperazine, R^1 = H
IIIh - R = diethyl amine, R^1 = -CH_2-diethyl amine
IIIi - R = pyrrolidine, R^1 = -CH_2-pyrrolidine
IIIj - R = morpholine, R^1 = -CH_2-morpholine

The new chemical entities were screened for 5-HT$_3$ modulator activities in Longitudinal Muscle Myenteric Plexus (LMMP) preparation of guinea pig ileum using Student's Physiograph. Compound IIIg exhibited comparable 5-HT$_3$ antagonist activity (pA$_2$-6.4) to that of standard antagonist Ondansetron (pA$_2$-7.4), while the other compounds exhibited mild to moderate 5-HT$_3$ antagonist activities. Compound IIIg could serve as lead molecule in this series for further study to obtain a clinically useful agent.

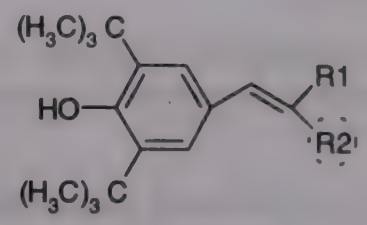
B32 A QSAR analysis of substituted 3, 5 di- tert – butyl (4- hydroxy) Styrene as anti-inflammatory agents

Geeta Kant and S.C. Chaturvedi[1]

Krupanidhi Collage of Pharmacy, No 5, Sarjapur Road, Korma gala Bangalore-34.

1. Department of Pharmacy, Shri Govindram Seksaria Institute of Technology and Science, 23- Park Road, Indore-452003 (M.P.).

A series of 19 anti-inflammatory drugs 3,5di tert butyl- 4- hydroxy styrene derivatives were subjected for (QSAR) quantitative structure activity relationship analysis, with an attempt to derive a co-relation between biological activity as dependent variable and various descriptors as Independent variables.



From the eight various descriptors many QSAR Equations were generated by stepwise multiple regression analysis. Out of four generated equations all the 19 analogues did not show significant cross co-relation. One of the four generated equations is given below.

BA= -1.08892 MR1 -0.203750 Hdor1 -0.23902 Hacc1

n =19 r = 0.729 r^2 =0.537 f =3.696 t =1.922 STD = 0.337———— (1)

Therefore to obtain a significant correlation coefficient, four analogues were eliminated from the data sets by leave one square method, and the equations obtained was,

BA = (-0.588016) MR1 + (0.2815) MR2 + (-0.150769) Hdor1 (-1.322597)

n=15 r =0.864 r^2=0.764 f =7.336 t=2.709 STD=0.64———————— (2)

From above equation (2), the negative value of (MR) at R1 shows steric hindrance and a positive value of MR at R2 show good binding dispersion forces between analogue and the receptor. And the correlation coefficient 'r' accounts for 86% variance in the biological activity value.

For further investigation of MR at R2, additional parameters like B5&L (Sterimol) were subjected for QSAR analysis. The following equation was obtained:

BA= 0.19827 R2L+-0.32270 R2B1+0.84462 R2B5+0.8442

n=15 r=0.475 r^2 =0.226 f=0.729 t=0.854 STD=0.281— (3)

The above Eq (3) is statistically not significant even though the over all value of B5 (Maximum width of substituent) is more contributing than L (Length of substituent) along the axis of parent skeleton. The QSAR analysis showed that the anti-inflammatory activity of the analogues is highly correlated with thermodynamic (MR) and Sterimol (B5, L) parameters. Hence Eq (2) & (3) indicates a less bulky substituent at R1and a more bulky lipophilic substituent at R2 is required for a good biological activity.

B_{33} Study of metal complexes of Ethambutol Dihydrochloride and Ciprofloxacin Hydrochloride

M. Mathrusri Annapurna*[1], S.D. Bhattamishra[2], M.E. Bhanoji Rao

1. Department of Medicinal Chemistry, Roland Institute of Pharmaceutical Sciences, Berhampur (Gm) 760 010, Orissa.
2. Department of Chemistry, Berhampur University, Orissa

The stability behaviour and the basicity constants were studied potentiometrically and spectorphotometrically with the two ligands (L) Ethambutol Di HCl (EB) and Ciprofloxacing HCl (CF) with metals copper and nickel in presence of KNO_3 at 25°C. The pKa values for EB are found to be 6.4 and 9.5 [Literature values are 6.6 and 9.5][1] and 6.2 for CF [Literature value 6.0][1]. All the spectral studies were performed between the wavelength 300 nm to 900 nm. Molar ratio study shows that at 600 nm and 690 nm the copper forms the compelxes with EB in 1:1 ratio in presence of sodium acetate (0.1M) and acetic acid (0.1 M) buffer system. The EB-Cu^{2+} complex (2:1) follows the Beer-Lambert law at 620 nm in ppm level concentration at pH ± 0.02. Potentiometric curves shows that the EB-Cu^{2+} complex formation start at a lower pH for a 1:2 system than for 1:4 system. Spectral studies for [EB] : [Eu^{2+}] = 10:1 system in presence of KNO_3 at different pH values shows that there are two isobestic points indicating that there are three different species in the system. The percentage distribution of species (Cu^{2+}, CuL, CuL_2) was further shown for both the ligands (L) the EB Di HCl and CF HCl. In the EB-Nickel study a single absorbing species was observed at a high pH = 10 with λ max at 485 nm is predominantly square planar. This compelx is in equilibrium with the octahedral trans isomer with at 374 nm and 612 nm. Absorption spectrum for Nickel - EB complex was studied at different time intervals ([EB] : [Ni^{2+}] = 2: 1 at pH < 9.2) in presence of KNO_3 which indicates that the peak at 485 nm drecreases within 5 mins and slowly vanishes in 48 hrs which may be due to the pH effect.

The copper and nickel complexes of both the ligands EB and CF has shown the antibacterial activity and further its anti cancer activity has to be studied.

B_{34} Synthesis and evaluation of prodrugs of selected non-steroidal anti-inflammatory drugs for analgesic and anti-inflammatory activity

Ashutosh Mishra, Hemant K. Jain, V. K. Dixit and R. K. Agrawal*

Department of Pharmaceutical Sciences, Dr. H. S. Gour Vishwavidyalaya, Sagar-470 003

The Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used for indications extending from inflammation and pain to cardiovascular and genitourinary diseases. Gastrointestinal side effects constitute the most frequent of all the adverse reactions of NSAIDs and lead to GIT ulceration and hemorrhage. Development of bioreversible derivatives by temporarily masking the acidic group of NSAIDs is a promising mean of reducing or abolishing the GI toxicities. In present study two well recognized NSAIDs viz Flurbiprofen and Ketorolac were selected. They suffer with gastrointestinal side effects. Various amino-acid ethyl ester amide prodrugs of Flurbiprofen and Ketorolac were prepared by amidation using acid chloride and acid anhydride of these drugs. Amino-acids possess very important physiologic characteristics such as they have healing effect on gastric lesions produced by NSAIDs, serve as dietary constituents, permit more specific targeting site for enzymes involved in terminal phase and alter solubility characteristic of drug when derivatized with them. Structural elucidation of prodrugs was done by various spectrophotometric methods. The physicochemical properties like solubility, partition coefficient, dissolution, protein binding, hydrolysis in biofluids and pharmacological screening for anti-inflammatory, analgesic and ulcerogenic activities were carried out.

On the basis of observations, it was concluded that prodrug approach could minimize gastrointestinal toxicity without loss of desired activities of the drugs. By proper selection of amino acid, partition coefficient, dissolution, hydrolysis and absorption can be regulated and thereby pharmacokinetic parameters can be modified.

B35 Synthesis and CNS activity of 5-(2-substitutedBenzoxazol-5Yl)-3-(N, N-disubst6ituted Aminomethyl) - 1,3,4-Oxadiazolin-2-thiones

B. Gopalkrishna*[1], N. Raghunandan, J. Venkateswar Rao, A. Venkatesham and M. Sarangapani

1. Karnataka B. Pharmacy College, Bidar
2. Medicinal Chemistry Laboratories, University College of Pharmaceutical Sciences, Kakatiya University, Warangal - 506 009

Twelve new 5-(2-substituted benzoxazol-5yl)-3 (N, N-disubstituted aminomethyl)-1,3,4-oxadiazolin-2-thiones have been synthesized by Mannich condensation of 5-(2-substituted benzoxazol-5yl)-1,3,4-oxadiazolin-2-thiones with different six seconday amines in presence of 30% formaldehyde solution. The intermediates on the other than hand have been prepared from 2-substituted benzoxazol-5-craboxylic acid hydrazide by reacting with carbon disulfide in alcoholic potassium hydroxide. The intermediates and the title compounds have been characterized by the chromatographic techniques and spectral data.

The compounds have been evaluated for their gross behavioural changes and effect on the locomotor activity by the standard protocols available in the literature. The results reveal that all the compounds have produced sedation and reduced the locomotor activity of the mice employed for the investigation. Compounds with dicyclohexylamino and diphenylamino groups have shown more effect on the reduction of the locomotor activity of the experimental animals.

B36 Indomethacin derivatives with a better pharmacokinetic and pharmacodynamic profile

K.K.Chagti *, P.K. Halen, R.Giridhar & M.R.Yadav

Pharmacy Department, Faculty of Technology & Engineering, Kalabhavan, M.S. University of Baroda.

Induction of gastric ulceration and bleeding on prolonged usage as side effect is common to most of the acidic NSAIDs. The topical effect is responsible for the local GI irritation which is due to the free carboxyl acid moiety, common to most of the acidic NSAIDs. Blocking of the carboxyl group temporarily has been done in past to abolish the local GI irritation involving the synthesis of esters and amides which release the parent drug after cleavage in the plasma. The objective of the present work was to prevent the topical effect by synthesizing some N,N-disubstituted b-aminoethyl esters of the indomethacin. The derivatives so designed would also satisfy the structural requirement for them to exhibit anticholinergic activity before cleaving to the parent drug. The anticholinergic activity was incorporated with the expected advantage of further decreasing the GI toxicity by decreasing the gastric acid secretion. All the synthesized derivatives were characterized by their physical and spectral data. All the compounds were found to be stable in pH 2.0 and 7.4 buffers and exhibited enzyme catalysed hydrolysis in 80% human plasma. Further all compounds showed anticholinergic activity when evaluated on rat ileum. Similar or somewhat less antiinflammatory activity was possessed by these derivatives and the parent compound at equimolar concentrations. Moreover, all the derivatives were found to be much less ulcerogenic than the parent drug at equimolar dosage.

C1 A new protease-fraction from the latex of calotropis procera

Subrat Kar*, Sanjita Das , S.P. Basu, S.K. Dutta

Seemanta Institute of Pharmaceutical Sciences, Jharpokharia 757086, Orissa.*

Calotropis procera (Fam. Asclepidaceae) is a popular medicinal plant widely distributed throughout the topics of Asia, Africa and is also widely grown throughout the length and breadth of India.

A new protein-fraction was extracted from the latex of *Calotropis procera* and it was found to possess proteolytic activity (through milk-clotting and caseinolytic digestion process) and it was given the name 'Calotropain P'. The temperature (t_{max}) and $_pH$ (max.) for getting at the maximum activity range of the enzyme were established and the values respectively are 60^0-65^0 and 5-8.

Studies of the temperature-dependence factor on milk-clotting yielded E_a (energy required to initiate clotting)=11.5Kcal/ mole and A (Arrhenius or frequency factor, a constant characteristic of the system)=3.2×10^8 min^{-1}. Its anti-helminthtic activity against earthworm of similar sizes was also evaluated . UV spectra showing peaks at $\ddot{e}_{max}$ =210nm and $\ddot{e}_{max}$= 230nm indicate the presence of –S- and –SH chromophoric groups in the moiety of the protein molecule.

C2 Chemical and pharmacological investigation of the flowers of Ervatamia coronaria

D. Satyanarayana*, Arun B. Joshi and Chandrashekar K.S.

NGSM Institute of Pharmaceutical Sciences, Nanthoor, Mangalore 575 005

There are a number of areas where modern medicine has not been able to provide a cure, but it only treats the symptoms. Some of the important diseases where we are still struggling to find a remedy are liver disorders, arthritic diseases and cancer. Future research programs in herbal medicines should be directed to find out effective and non-toxic, therapeutic agent of such diseases.

In the traditional system of medicines various parts of the plant are used in treatment of opthalmia, for application of wounds and inflammed parts of the body, as an anthelmintic etc. Anticancer activity has also been reported from the crude extracts of the plant. A number of indole alkaloids have been reported from the leaves, stems and roots of this plant. Since the chemical investigation of the flower of Ervatamia coronaria has not been reported and in spite of its use in liver disorders, no systematic studies on liver protective activity have been reported in the literature. Hence, an effort was made to establish both the chemical investigation as well as hepatoprotective activity of the chloroform extract of the flowers of Ervatmia coronaria.

The chloroform extract, which was eluted using Cloroform: Methanol (50:50) resulted in four compounds. They gave positive reactions for general tests for alkaloids. These four compounds were identified as Harmine, Voacristine, Heyneanine and Apparicine based on their MP, IR, ^{1}HNMR and MASS spectral data. The chloroform extract of the flowers of *Ervatamia coronaria* were tested for hepatoprotective activity and the results indicated that there was lowering in the serum enzyme levels like SGOT and SGPT thus proving the hepatoprotective activity in rats intoxicated with Carbon tetra chloride.

C3 *In-vitro* cytotoxicity study of the alkaloidal fraction of the unripe fruits of *Solanum indicum* and *Solanum xanthocarpum* against human cancer cell lines

Bibhuti. B. Kakoti*[1], G.P. Senthilkumar[1], L. Manikandan[1]*, S. Bhattacharya[1], Sutapa Chakraborty[2], Madhumita Ray[2], U. K. Mazumder[1] and M. Gupta[1]

Dept. of Pharmaceutical Technology, Jadavpur University, Kolkata
Chittaranjan National Cancer Institute, Kolkata

Alkaloidal fraction of the unripe fruits of *Solanum indicum* and *Solanum xanthocarpm* were evaluated for their cytotoxicity against four human cancer cell lines acute myeloblastic leukemia (HL60), chronic myelogenic leukemia (K562), cervical epithelial carcinoma (HeLa) and breast adenocarcinoma (MCF-7). Cytotoxicity was assayed by 3-(4,5-dimethy1 thiazole-2yl)-2,5-dipheny1 tetrazolium bromide (MTT) reduction assay and trypan blue dye exclusion assay. [^{3}H] thymidine uptake assay was also carried out to study the effect of the extracts on cell proliferation.

The alkaloidal fraction of *Solanum indicum* exhibited strong cytotoxicity against the tested cell lines in a dose dependent manner whereas the alkaloidal fraction of *Solanum xanthocarpum* was found to be less effective against MCF-7 cell line at the tested concentrations. Thus from the present investigation it can be concluded that the alkaloidal fractions of *Solanum indicum* and *Solanum xanthocarpum* exhibited cytotoxicity in human cancer cell lines.

C4 A new ceramide from the sponge *Iotrochota baculifera* ridley of the indian ocean

P. Muralidhar, N. Krishna
Ch. Bheemasankara Rao[1], D.K.M. Lakshmi* and
D. Venkata Rao

Dept. of Pharmaceutical Sciences, Andhra University
[1]School of Chemistry, Andhra University,
Visakhapatnam

Marine metabolites are known to produce bioactive compounds. As part of our continuing search for bioactive compounds from marine organisms, we have investigated *Lotrochota baculifera* Ridley. Previous studies on sponges of the genus *Lotrochota* have resulted in the isolation of structurally new ceramides, ecdysteroids, bromoindole alkaloids etc. Among these some metabolites showed potential biological activities such as antitumor, anti-inflammatory, antiviral and antibacterial activities.

The sponge, collected from the Tuticorin coast of the Indian Ocean, was washed thoroughly with fresh water at the site and preserved in methanol. The organism was extracted using methanol and concentrated. The residue was fractionated with ethyl acetate and ethyl acetate fraction was chromatographed over silica gel column. The column chromatography yielded compound 1 along with butyl alcohol and monohydroxy sterol mixture. The compounds 1 was further purified by medium pressure liquid chromatograph yielded pure compound. The Compound 1 was characterised as (2S, 3S, 4R)-2-[(2R, 4E)-2-hydroxy-4-tetracosenoylamino]-1, 3, 4-trihydroxy-octadecane on the basis of ^{1}H and ^{13}C NMR, DEPT, COSY and FABMS experiments.

C5 Gymnemic acid from callus of leaf explant of *Gymnema sylvestre (Retz.) R. Br.*

Sujani Nayak, Shashidhara S and Puttaswamy K

Department of Pharmacognosy, Government College of Pharmacy, Bangalore 560 027, India.

Gymnema Sylvestre (Retz.) R. Br. is a valuable medicinal plant belongs to family *Aspidiaceae*. Leaves of the plants are well known in traditional medicine to control diabetes and are also used as digestive, liver tonic and diuretic. Gymnemic acid is the active constituent. It is a triterpenoidal saponin having an antisweet property. Increased demand for this drug has lead to depletion of this plant, hence this work was undertaken to produce gymnemic acid from callus produced using leaf part of *Gymnema sylvestre*.

Leaf explant was used for initiation of callus on B5 media supplemented with NAA (2mgl) & BAP (1mg/l), cultures were then incubated at 24±2°C dark condition. The callus produced was subcultured on fresh media supplemented with similar hormone concentration Callus proliferated was dried and subjected to extraction using methanol. Methanolic extract was further subjected to fractional separation using butanol after acidification. A TLC study of isolated compound confirms it to be pure and have similar character as that of standard Gymnemic acid. UV. IR and NMR spectral values of isolated compound and comparison of values with standard Gymnemic acid also confirms that isolated compound is Gymnemic acid.

C6 Immunostimulant & free radical scavenging activity studies of *Ganoderma applanatum*

Lins Mary Joy* & M.C. Divakar

Grace College of Pharmacy, Athalur, Kodinithirapully, Palakkad - 4, Kerala

Ganoderma lucidum is a well known Chinese medicine due to its outstanding medicinal properties. The present work is envisaged to screen the immunostimulant and antioxidant activity of a closely related species, *Ganoderma applanatum*. The fruiting bodies were collected in January 2003 from the Agricultural College, Trivandrum and identified at the plant Pathology Department of this College.

Mycological studies including determination of crude fibre content, ash and extractive values were carried out as a mode of identification of the drug.

The qualitative analysis showed the presence of steroidal triterpines. A single compound was isolated by column chromatography with the solven dichloromethane : chloroform in the ration 1:1 and the spectral values of this compound (GAC_4) correlated with the isolated compound lucidadiol. The HPTLC analysis showed six different spots with Rf values 0.23, 0.28, 0.30, 0.39, 0.45 and 0.54. Quantification was carried out using the isolated compound (lucidadiol) as the marker. And the result showed 82.5 mg/g of lucidadiol in the total extract.

Acute Toxicity studies (fish lethal toxicity) were carried out with various concentration of the extract and derived dose response curve for GAE (concentration vs. percentage mortality). LC_{50} and LD_{50} were determined as 875 mg/ml and 707.9 mg/ml respectively.

The free radical scavenging activity was screened in-vitro by measuring the percentage reduction in the absorbance of the drug at a concentration of 100 µg/ml. The hydroxyl, superoxide, lipid peroxide radical scavenging activities showed EC_{50} values of 56.28, 51 mcg/ml and 62, 31.5 66 mcg/ml for GAE and GAC_4 respectively. The study showed that the drug can be used as a substitute for *Ganoderma lucidum* and as a very god immunostimulant and free radical scavenging activity with less toxicity.

C7 Phytochemical and pharmacological investigation of fruits of *Capparis moonii hook. f. thoms*

R. Ramachandram, Mohd. Ali, Showkat R. Mir*, Abdul Wadood & Reni Kapoor

Department of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi-110062

Capparis moonii Hook. f. Thoms. (Family *Capparidaceae*), commonly known as Rudanti, possess anti-tubercular activity. Phytochemical investigation of an ethanolic extract of the fruits of C. moonii Hook. f. Thoms. resulted in the isolation of n-tricosa-17-on-1-oic acid (capparitricosanoic acid), stigmasta-5-en-3b-ol (b-sitosterol) and 24 S-stigmasta-5,7-dien-3b-ol (moonisterol). Their structures have been elucidated on the basis of spectroscopic data analysis and chemical means. The ethanolic extracts of fruits of *C. moonii* showed significant hepatoprotective activity in carbon tetrachloride-induced hepatotoxicity in rats compared to silymarin while as analgesic activity was non-significant in acetic acid-induced writhing in mice.

C8 Antihyperlipidemic activity of ethanol extract of *Terminalia arjuna*

N. Mahadevan, P. Bikash Kumar, E.P. Kumar, G. Navin Kumar* and B. Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund-643001, The Nilgiris, Tamilnadu

The 95% ethanol extract of bark of *Terminalia arjuna* W&A was evaluated for antihyperlipidemic activity by triton-induced hyperlipidemia in Wistar albino rats. The ethanol extract was prepared by maceration with 95% ethanol and subjected for antihyperlipidemic screening. Adult male albino rats of Wistar strain, weighing about 150 - 200gm were used. The ethanol extract at a dose of 250 mg per kg and 500mg per kg body weight were administered to rats by oral route for 7 days. Atorvastatin is the standard antihyperlipidemic drug was administered at a dose of 1.2mg per kg of body weight. Hyperlipidemia was induced by injecting triton at a dose of 200mg per kg body weight. The rats were anesthetized with diethyl ether and blood was collected by intra orbital puncture after 6th hour, 24th hour and 48th hours of triton injection. The blood was collected in tubes containing 10micro liter of trisodium citrate as anticoagulant. Plasma was separated from blood by centrifugation and used for biochemical estimation of cholesterol and triglycerides using auto analyser (Merck Microlab-200). The E-Coline kits were used for the estimation of cholesterol and triglycerides. A rise in cholesterol and triglycerides levels were observed in triton administered rats, whereas the rats administered with 95% ethanol extract and atorvastatin showed significant reduction of cholesterol and triglycerides levels at 6th, 24th and 48th hours. The ethanol extract at 500mg per kg body weight showed significant reduction of triglycerides at 6th and 24th hour, where as 250mg per kg body weight showed a significant reduction only at 6th hour. The activity of extract was compared with atorvastatin. The experiment showed the dose dependent antihyperlipidemic activity of *Terminalia arjuna* bark.

C9 Antihyperlipidemic activity of combined extract of *Cynara scolymus* and *Zingiber officinale*

N. Mahadevan, B. Anurag, M. Ramanathan, S. Hemant Kumar* and B. Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund-643001, The Nilgiris, Tamilnadu

The aqueous extract of *Cynara scolymus L* (artichoke) and oleoresin of *Zingiber officinale* (zinger) were combined and evaluated for antihyperlipidemic activity by triton-induced hyperlipidemia in Wistar albino rats. The plant extracts were combined with respect to their individual doses and subjected for antihyperlipidemic screening. Adult male albino rats of Wistar strain weighing about 150- 200gm were used for the study. The extract was administered by oral route for 6 days. *Hyperlipidemia* was induced by injecting triton at a dose of 0.1ml/100 gm body weight. On 7th day, the rats were anesthetized with diethyl ether and blood was collected by intra orbital puncture after, 24th hour and 48th hours of triton injection. The blood was collected in tubes containing 100 micro liter of trisodium citrate as anticoagulant. Plasma was separated from blood by centrifugation and used for biochemical estimation of cholesterol and triglycerides using autoanalyser (Merck microlab-200). The *E-Coline* kits were used for the estimation of cholesterol and triglycerides. A rise in cholesterol and triglycerides levels were observed in triton administered rats, whereas the rats administered with combined extract shows significant reduction of cholesterol and triglycerides levels at, 24th and 48th hours. Hence it can be concluded that, the combined extract possess antihyperlipidemic activity against triton induced hyperlipidemia.

C10 Phytochemical and pharmacological investigation of *Phyllanthus lawii*

Chandrashekar K.S.*, Sathyanarayana D., Arun B. Joshi

Dept. of Pharmacognosy NGSM Institute of Pharmaceutical Science, Nanthoor, Mangalore 575 005

Phyllanthus lawii belonging to the family Euphorbiaceae grows abundantly in South Canara and is used by the natives particularly for the treatment of jaundice. No report of Phytochemical investigation on *Phyllaanthus lawii* has been published so far and a very few reports of pharmacological investigation has been published. Therefore it has been planed to carry out systematic studies such as isolation of active constituents, characterization and to study hepatoprotective activity.

The aerial parts of *Phyllanthus lawii* were exhaustively extracted under reflux with 95% ethanol. The extract was suspended in distilled water and extracted with petroleum ether (60-80°C) and evaporated to dryness. The residue was subjected to neutral alumina column to yield three compounds. The compounds were characterized by IR, ^{1}H NMR,^{13}C NMR, and Mass spectral analysis and were confirmed as a-amyrin acetate, β-sitosterol and stigmasterol.

The petroleum ether extract was evaluated for antihepatotoxic activity. The enzymatic levels and histopathological observations revealed that the Petroleum ether extract of aerial parts of *P.lawii* impart significant hepatoprotection in carbon tetrachloride induced injury. It may be presumed that a-amyrin acetate , b-sitosterol and stigmasterol are the active components responsible for the antihepatotoxic activity.

C11 Investigation of the leaves of *Lagenaria vulgaris*

Arun B. Joshi*, D. Satyanarayana and Chandrashekhar K.S.

Department of Pharmacognosy NGSM Institute of Pharmaceutical Science, Nanthoor, Mangalore 575 005

The greatest contribution of plant kingdom to mankind is allevation of suffering from diseases by providing a large variety of potent drugs. Inspite of the spectacular advances in synthetic drugs, there is a tendency to use indigenous drugs and natural products wherever possible, obviously because of their low cost and relative lack of serious side effects. This is especially true in developing countries like India. Even in a highly developed country like USA, a quarter of all the prescriptions dispensed had either crude extracts of plants or pure drugs isolated from plants or even formulations.

In the traditional system of medicine, various parts of the plant are used in the treatment of leucorrhoea, vaginal and uterine complaints, diuretic, cardiotonic, aphrodisiac, inflammations, emetic and purgative. A number of triterpinoids, Triterpinoid saponins, flavonoids and sterols have been reported from the seeds, roots, and fruits of *Lagenaria vulgaris*. Since the chemical investigation of this plant has not been reported and inspite of its use as an anti-inflammatory, no systemic study has been reported in the literature. Hence, an effort was made to establish both the chemical investigation as well as anti-inflammatory activity of the petroleum ether extract of the leaves of *Lagenaria vulgaris*.

The petroleum ether extract, which was eluted using petroleum ether : benzene (80:20) resulted in three compounds. They gave positive reactions for triterpinoids. These three compounds were identified as a- amyrin acetate, b-amyrin acetate and lupeol based on their MP, IR, ^{1}HNMR and MASS spectral data .The Petroleum ether extract of the leaves of *Lagenaria vulgaris* was tested for Anti-inflammatory activity. The results indicated that the petroleum ether extract of the leaves of *Lagenaria vulgaris* showed moderate anti- inflammatory activity.

C12 Studies on the anti-inflammatory and free - radical scavenging activities of Sea cucumber and Cuttlefish glandular extracts

R. JayaPrakasam*, Madhu C. Divakar

College of Pharmacy, SRIMPS, Coimbatore 641 044

The glandular extracts of *Holothuria scabra (Sea cucumber)* and *Sepia pharaonis (cuttlefish)* were prepared using chloroform:methanol (1:1) solvent mixture. Qualitative chemical analysis indicated the presence of steroids in these extracts. Human RBC membrane stabilizing action was utilized for screening the anti-inflammatory activity of these steroidal fractions. The free radical scavenging studies were performed by utilizing invitro model of hydroxyl and lipid peroxide radical generating systems as these two radicals are the major causative agents of inflammation.

Results indicated that the *Cuttlefish* and the *Sea Cucumber* glandular extracts (CFE & SCE) at 100mg / ml concentration showed; 52.26 % and 49 .0 % protection of HRBC in hypotonic solution, 77.82% and 71.54 % hydroxyl radical scavenging activity and 56%& 68% lipid peroxide radical scavenging activity. The toxicity studies were performed using brine shrimp *(Artemia salina)* assay method. The LC_{50} values obtained for CFE & SCE were 610 mg /ml and 430mg/ ml respectively.

Currently there is greater interest on certain marine organisms; as they can serve as rich sources

of various chemical compounds with interesting pharmacological actions like anti cancer, anti inflammatory, anti arthritic, antimicrobial activities etc. *Sea Cucumber* and *Cuttlefish* are used extensively for the treatment of kidney dysfunction, arthritis, anemia, impotency, blood disorders etc in the Chinese traditional system of medicine. Survey of literature indicated that the glands of *Sea Cucumber & Cuttlefish* contain several lanostanetype of triterpene oligoglycosides; glucosaminoglycans, isocaffeine derivatives, fucosylated polysaccharides etc. In the light of the above findings, it is decided to screen the anti- inflammatory & free radical scavenging activities of the glandular extracts of these two marine organisms.

Results of the anti-inflammatory activity indicated that both CFE & SCE produced significant protection of HRBC in hyposaline. CFE & SCE at 100 mg / ml concentration showed at 52.26 % and 49.0% protection of HRBC in hypotonic solution; While Betamethasone (50 mg/ml) showed 48.14% protection of HRBC in hyposaline.

The anti-inflammatory activity of CFE & SCE may be due to the inhibition of some enzymes like cyclooxygenase, lipooxygenase etc which are present in HRBC membrane similar to that of lysosomal membranes, Prostoglandins are produced from arachidonic acid pathway utilizing cyclooxygenase enzyme, in the inflammation process. The prostoglandin production can be inhibited by blocking these enzyme activity and these by reducing the inflammation. Therefore it is suggested that the anti-inflammatory activity of the extracts CFE and SCE may be due to the blockade of these HRBC membrane enzymes like cyclooxygenase and also by scavenging the hydroxyl and the lipid peroxide free radicals.

C_{13} Evaluation of antihyperlipidemic activity of aqueous extract of *Lagenaria siceraria* (Mol.) Standl. fruits in rats.

Hase D. P.*, Pandit S. S., Ghule B. V. and Saoji A. N.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur-440 033.

Lagenaria siceraria (Cucurbitaceae) fruits commonly known as 'Lauki'. Traditionally fruits have been used for emetic, aphrodisiac, alexiteric, cooling, cardiotonic, inflammation, ulcers, pain diuretic and antibilious properties.

Aqueous extract of fruits of *Lagenaria siceraria* evaluated for the antihyperlipidemic activity in an athergogenic diet-induced hyperlipidemia, in Male Albino rats. (weighing about 150-250gm) were used for the study. The animals were divided into five groups each comprising six rats. The extract was administered by oral route (100 and 200mg/kg). Hyperlipidemia induced by feeding 400mg/kg cholesterol in 5 ml coconut oil with standard pellet diet. Gemfibrozil 10mg/kg was taken as the standard drug. After nine days the animals were starved for 24 hr. and they were anaesthetized with diethyl ether and blood was collected from the retro-orbital plexus of the eye. Serum was separated by centrifuging the blood at 1000 rpm and stored in freeze until analyzed.

Serum was analyzed for biochemical estimation of cholesterol (C), HDL-C, LDL-C, VLDL-C and triglycerides using auto analyzer (Merck Microloab 200). E coline kits were used for the estimation of cholesterol and triglycerides. Atherogenic index (A.I.) is calculated from various cholesterol levels.

Aqueous extract found to be statistically decrease in the serum total cholesterol and triglyceride level ($P<0.01$). A rise in cholesterol and triglyceride were observed in the diet-induced hyperlipidemia, and significant increase in HDL-C in aqueous extract treated rats, atherogenic index is less than hyperlipidemic diet group.

Hence it can be concluded that the aqueous extract possess antihyperlipidemic activity against diet-induced hyperlipidemia.

C_{14} Antimicrobial activity of callus cultures of leaf and stem of *Convolvulus microphyllus Sieb.*

R. Zafar*, Sayeed Ahmad, and Mohd. Mujeeb

Plant Tissue Culture Laboratory, Department of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi -110062.

Convolvulus microphyllus Sieb is a very important medicinal plant, commonly known as *Shankhpushpi.* Callus cultures of leaf and stem explants have been initiated and maintained in MS basal medium supplemented with various plant growth regulators viz 2, 4-D, 6-BA, IAA and Kin (1 ppm each). The dried and powdered leaf, stem and 60 days old leaf and stem callus were separately extracted with petroleum ether, chloroform and alcohol for phytochemical screening. It was found that alkaloids, amino acids, ascorbic acid, coumarin, carbohydrate, phenolics, proteins, saponins and steroids were present in all samples. Flavonoids were present in natural leaf and stem extracts but absent in leaf and stem calli.

The antimicrobial activity of water soluble methanolic extract of leaf, stem and their 60 days old calli were carried out by cup plate method against *Staphylococcus aureus* (gram positive) and *Escherichia coli* (gm negative) bacteria using ampicillin (20 mgm / ml) soln as reference standard. All the extracts showed antimicrobial activity at 500 mgm / ml concentration, which is less than the standard

ampicillin soln (27 mm). Maximum zone of inhibition was observed with leaf callus extract against gram positive bacteria followed by leaf and stem extracts (17 mm). How ever no antimicrobial activity was observed with 250 mgm / ml concentration of all extracts.

Results obtained in present investigation reveals that the cultures produced in-vitro can be used as an alternative source of biomass of *Convolvulus microphyllus* for the production of secondary metabolites which are useful in various ailments and infections.

C15 Hypoglycemic activity of flowers of *Cassia auriculata* Linn.

Basavaraj. Hatapakki*., G.R. Shendarkar and Suresh H.M.

KLES's College of Pharmacy, JT College Campus, P.O. Box 23, Gadag 582 101. Karnataka

Cassia auriculata linn, family - *Ceasalpiniacea* is a shrub with large bright yellow flowers, widely distributed in dry regions, popularly known as *Tanner's senna*. It possesses encouraging scope in Indian system of medicine for its astringent, alterative and antidiabetic properties. The plant is traditionally used in the treatment of conjunctivitis and various disorders of G.I.T. Mutalik.S, et.al evaluated and reported the antidiabetic activity of *Dianex* an herbal preparation in which *Cassia auriculata* flowers is one of the component.

In the present study, the authenticated flowers of *Cassia auriculata* were collected in the right season from surrounding areas of Belgaum Dist. The shade dried, powdered flowers were Soxhlet extracted with 95 % ethanol for 48 hours. The extract further concentrated to dryness under reduced pressure in vacuo. Some part of the extract is reserved for activity and rest is subjected to determination of unsaponifiable matter (U.S.M) as per method described in I.P. 1966.The above extract and U.S.M. were evaluated for Hypoglycemic activity against alloxan induced diabetes in rats including different biochemical studies like estimation of fasting blood glucose level, estimation of total cholesterol and HDL cholesterol and estimation of triglycerides compared with standard reference Glibenclamide.

The ethanolic extract and USM significantly ($P<0.01$) reduced the fasting Blood Glucose level, total cholesterol & HDL cholesterol level and triglyceride level. It can be inferred that ethanolic extract and USM possess significant Hypoglycemic and Hypocholesterimic activity in a concentration of 200 mg/kg ethanolic extract and USM respectively.

C16 Phytochemical and pharmacological investigation on *Ceiba pentandra* (Linn). Gaertn.

A. Thanga Thirupathi*, J. Anbu Jeba Sunilson, V. Alphonsa, V.V. Deepa, P.S. Geetha, C. Venkat Gurubaran and R. Venkat Narayan.

Dept. of Pharmacology, SB College of Pharmacy, Sivakasi 626 130.

The dried powdered root of *Ceiba pentandra* was subjected to different solvent extraction and the extracts were dried and the percentage yield was calculated. From the presence of phyto constituents in various extracts, three extracts namely ethanolic, aqueous and total aqueous were selected for pharmacological studies. The three extracts were evaluated for locomotor activity, purgative activity and diuretic activity.

Phytochemical analysis revealed that there is presence of alkaloid, carbohydrate, glycosides, phytosterols, phenolic compounds, tannins, proteins, aminoacids, gums, mucilages and flavanoids in the three test extracts. The locomotor activity results revealed that all the test extracts showed significant depressant property in the order aqueous and ethanolic in an equivalent manner followed by total aqueous extract. The purgative potency first lies with ethanolic followed by aqueous second followed by total aqueous extract last.

All the three extracts showed significant diuretic activity in the order aqueous first followed by total aqueous second followed by ethanolic extract last. All the three test extracts possess naturetic, kaliuretic, chloruretic and aqueretic properties.

The three test extracts viz aqueous, total aqueous and ethanolic extract showed the presence of pharmacologically active physoconstituents like alkaloid, glycosides, phenolic compounds, tannins, and flavonoids. All the three test extracts showed different degrees of CNS depressant, purgative and diuretic activities.

C17 Evaluation of wound healing and antimicrobial activity of tannins of *terminalia arjuna*

Minakshi C*. and Mengi S.

C.U. Shah College of Pharmacy, SNDT Women's University, Juhu, Santacruz (W), Mumbai 400 049

The bark of the plant *Terminalia arjuna* Family *Combretaceae* has been mentioned to be effective in wound healing by Sushruta in Sushruta Samhita. The present study was conducted to evaluate tannins of *Terminalia arjuna* for wound healing activity with a supportive study of antimicrobial activity.

Incision and excision wound models were inflicted under anesthesia in albino Wistar rats. Tannins of the plant prepared as 0.1%, 0.5% and 1% w/w simple ointment were evaluated topically in the rats. Tensile strength for incision and percent closure of wounds for excision wounds were measured. Since the post operative wounds are known to be complicated with infections, additionally tannins of the plant were evaluated for antimicrobial activity as supportive evidence toward wound healing activity of the plant at concentrations (5-200 mg/ml) against *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Streptococcus. pyogenes* and *Candida* albicans by the cup plate method.

Results indicate tannins of the plant to reveal wound-healing activity. The tensile strength of the incision wound and the percent closure of the excision wound was increased in dose dependent manner as compared to control. The efficacy of the tannins was found to be better than the hydro alcoholic extracts in both incision and excision wound models. Additionally the tannins of the plant also demonstrated antimicrobial activity against all the organisms except *Candida albicans,* thus validating the traditional claim of the plant as wound healing agent.

C18 Evaluation of anti-microbial activity of methanolic extract of root of *Asparagus racemosus* willd

N. Venkatesan*, R. Vadivu, J. Britto Perianayagam, S. Murugesan, R. Sankar, P. Thirumal

Faculty of Pharmaceutical Science Guru Jambhushwar University, Hisar 125 001, K. P. College of Pharmacy, Tiruvannamalai 606 603.

Asparagus racemosus Willd (Liliaceae) is a well known traditional Ayurvedic medicine which has proved to be immune value in a wide variety of diseases. The methanolic extract of *Asparagus racemosus* Willd was investigated for its antimicrobial activity against for antibacterial (*Escherichia coli, Staphylococcus aureus*) and antifungal (*Aspergillus niger. Aspergillus flavus, Saccharomyces cereviseae* and *Candida albicans*) using plate disc method. The extract showed significant antimicrobial activity and were comparable to standard antibacterial chloramphenicol) (10mg/ml), Antifungal amphotericin (10mg/ml). Our findings confirm the traditional therapeutic claims for this herb. The results shown very good antimicrobial property of methanol plant extract.

The plant has shown enormous possibilities of research on the phytochemical and pharmacological activities. Further research work had been done in Pharmacognosy and Pharmacological oriented and it showed significant activity on anti-diarrhoeal.

The antibacterial activity of root is more than that of leaves. Our findings confirm the traditional therapeutic claims for this herb, in near future surely be able to replace the conventional antimicrobial agents to which there is increased incidence of drug resistance.

C19 A new sphingosine derivative from the indian ocean gorgonian *Pseudopterogorgia australiansis*

N. Krishnan, P. Muralidhar, M. Murali Krishna Kumar, D. Benkata Rao* and Ch. Bheemasankara Rao[1]

Department of Pharmaceutical Sciences, Andhra University, [1]School of Chemistry, Andhra University, Visakhapatnam

Extensive studies on marine invertebrates have resulted in the isolation of terpenes, unusual highly oxygenated sterols and other compounds. As a part of our continuing study on the metabolites of marine organisms, we have investigated a gorgonian *Pseudopterogorgia australiansis* collected from the coasts of the Indian Ocean. *Gorgonians* (Phylum : *Coelenterata*) are known to be a rich source of a variety of secondary metabolites, namely, novel sterols, prostaglandins, terpenoids. polyhalogenated compounds and sphingolipids. Herewith we are reporting the isolation and characterization of a new sphingosine derivative.

The gorgonian, collected from the Tuticorin coast of the Indian Ocean, was washed thoroughly with fresh water at the site and shade dried. The gorgonian was powdered and the powder was extracted with MeOH eight times. The combined alcoholic concentrate was fractionated with ethylacetate and was chromatographed over silica gel using eluents with increasing polarity starting from n-hexane through EtOAc to MeOH. On silica gel chromatography of the high polar fractions yielded a white solid which on further, purification on medium pressure liquid chromatograph (MPLC) gave colourless crystals of sphingolipid (1). The structure of the new sphingosine derivative was derived as (2S, 3S, 4R)-1, 3, 4-trihydroxy-2-[(R) - 2^1 - hydroxynonadecanoyl) amino] nonadecane (1) on the basis of ^1H and ^{13}C NMR, COSY and FABMS experiments.

C20 Separation, identification and standardisation of plant constitutents of *Acacia catechu*

S Patil*, S Narayanan+ and C I Jolly*

*# Department of Pharmacognosy and Phytochemistry

K M Kundnani College of Pharmacy, 47, R G Thadani Marg, Worli, Mumbai - 400 018, India.

Quest Institute of Life Sciences, Mulund, Mumbai. Dr. Swati Patil, K M Kundnani College of Pharmacy,

47, R G Thadani Marg, Worli, Mumbai - 400 018, India.

The emphasis today, alongwith herbal medicine is given to natural product chemistry, which includes the isolation and structure determination of wide array of compounds. Such studies are made possible by introduction of new techniques of separation and analysis. Not all chemical compounds elaborated by plants are of equal interest to a pharmacognocist. The so-called "active principles" thus deserve special attention. Herbal medicines are prepared from materials of plant origin, which are prone to contamination, deterioration and variation in composition. The antimitotic activity of A. catechu is established in a separate investigation. It was hence thought worthwhile to separate, isolate, characterise and standardise the constituents of interest from the total extract. Standardisation was done accordingly to WHO monograph for standard for herbal drug. The standardisation was carried out by UV and HPTLC methods. Preparative chromatographic technique was used to separate the constituents. Isolated fractions were subjected to IR, UV, NMR, elemental and MS analysis. Identification, structure identification and derivation of empirical formula were done with the above interpretation.

C21 *In-vitro* and *in-vivo* antioxidant activity of *Moringa oleifera*

Munish Garg*, Chanchal Garg, Pulok K. Mukherjee, S.S. Badami & B. Suresh

J.S.S. College of Pharmacy, Ooty (Tamilnadu) – 653001.

It is evident that oxidative damage has been implicated in many degenerative diseases like liver damage,arthritis, aging, cardiovascular disorders, diabetes mellitus, cancer neurological disorders etc. Hence oxidative damage needs to be prevented. *Moringa oleifera* is a widely used plant in Indian families. Besides this, the plant exhibit excellent medicinal properties. The present study is based on the evaluation of antioxidant potential of *Moringa oleifera*. Methanolic leaf extract of the plant was investigated for in vitro effect of oxidative damage induced by UV-radiations to the *Salmonella typhi bacteria* and in vivo effect on the production of body enzymes i.e. catalase and superoxide dismutase.The measurement was also done on the formation of malondialdehyde in terms of thiobarbituric acid reactive substances in blood and brain of male albino wistar rats. The plant extract has shown significant antioxidant potential by inhibiting the oxidative damage caused by UV-radiations resulting in increased number of colonies as compare to the control. It has also shown good activity by increasing superoxide dismutase production in the blood but shown no significant change in catalase level. The extract has significantly reduced the MDA formation in blood and brain of experimental animals. This confirms the antioxidant potential of plant both in vivo and in vitro.

C22 Coumarinolignoids from *Hyoscyamus niger*

Sajeli Begum. A* and Mahendra Sahai.

Department of Medicinal Chemistry, Institute of Medical Sciences, Banaras Hindu University, Varanasi 221 005.

Hyoscyamus niger Linn. (Fam. : Solanaceae) Eng. : Henbane, is an erect and coarse herb, widely distributed in India i.e. from Kashmir to Garhwal Himalayas. The genus Hyoscyamus, a rich source of tropane alkaloids possessing mydriatic, analgesic and antispasmodic properties, is also found to be reported for some withanolides. Two coumarinolignoids designated as HN-I and HN-II have been isolated and characterized from the methanolic extract of seeds of *Hyoscyamus niger*.

A specimen sample of raw material used for investigation has been preserved in the Department of Medicinal Chemistry, Institute of Medical Sciences, Banaras Hindu University, Varanasi. The dried and powdered seeds of *Hyoscyamus niger* was Soxhletted successively with n-hexane and methanol. The chromatography of methanolic extract resulted in the isolation of HN-I and HN-II.

HN-I, $C_{20}H_{18}O_8$, M^+ at m/z 386, m.p. 247-250°C, $[a]_D \pm 0°$, was identified as Cleomiscosin-A, a coumarinolignan, on the basis of detailed spectroscopic analysis. HN-II, $C_{20}H_{18}O_8$, m.p. 272 - 274°C, $[a]_D \pm 0°$, was identified as Cleomiscosin-B, a congener of Cleomiscosin-A. The regioisomeric pairs Cleomiscosin-A and Cleomiscosin-B were found to be isolated and characterized for the first time from this plant species as well as from the family Solanaceae itself.

C23 Preliminary phytochemical investigations and adaptogenic activity of fruit pulp of *Feronia elephantum* corr.

Vivek V.Byahatti*, Marina G.D'Souza, Anurag Mishra, V.I.Hukkeri, Vijay Singh

K.L.E.S' College of Pharmacy, Vidyanagar, Hubli, Karnataka.

The present study was carried out to identify various phytoconstituents of fruit pulp of *Feronia elephantum* & to evaluate adaptogenic (immunomodulatory) effect of the same. The plant Feronia elephantum is a monotype, moderate sized tree of family Rutaceae. The fruits of which are around

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6 cm in diameter, hard, gray in colour, known as wood apple or elephant apple, favorite fruit of Lord Ganesha. The 95% ethanolic extract of fruit pulp of feronia elephantum was found to contain flavonoids, carbohydrates, and amino acids as its constituents by chemical tests. Successive solvent extraction with various organic solvents of different polarity was carried out. The ethyl acetate extract was found to contain flavonoids as its constituents by chemical tests. TLC & Spectral studies confirmed the presence of the same. The total ethanolic extract of fruit pulp of feronia elephantum at a dose of 500-mg/kg body weight showed promising & significant adaptogenic effect for parameters studied.

C_{24} Evaluation of antimicrobial and cytotoxic activities of *Sphaeranthus indicus in-vitro*

Prashanth Kumar V., Padh H., Rajani M.

B V Patel PERD Centre, Thaltej Gandhinagar Highway, Thaltej, Ahmedabad 380 054

Although substantial progress has been made in chemotherapeutic design and implementation, infectious diseases and cancer remain insidious. The number of deaths related to these continues to increase and systemic chemotherapy remains the primary method of attacking disseminated disease, and there is clearly a need for the discovery of newer agents. The use of natural products of plant origin for the treatment of diseases, especially in various infectious conditions and malignancy dates back to more than 3,500 years. But only a small fraction of the world's biodiversity has been scientifically evaluated for various biological activities. Thus it is reasonable to assume that additional agents are in existence that remain to be uncovered. A conservative estimate reveals that there are 250000 species of plants in the world which remain to be explored for their various activities. This prompted our interest in evaluating the natural products as potential chemotherapeutic agents. In this effort we have screened a number of plants based on their ethnomedical use, for antimicrobial and cytotoxic activity invitro. In this paper we present our work on the plant Sphaeranthus indicus commonly known as Gorakh mundi, which showed significant activity.

Dichlormethane: methanol (1:1) (DCM) extract of various parts of *S. indicus* were evaluated for antimicrobial activity against a range of microorganisms including bacteria and fungi by agar streak method. Minimum inhibitory concentration of the extract of the flower head was determined against both test strains and clinical isolates by disc diffusion method. Bioautographic studies were carried out to identify the active compound. Cytotoxicity and inhibition of cell proliferation was evaluated against HepG2, HEp2 and HeLa cell lines by MTT assay. Chemoprofiles of these extracts have been developed using High Performance Thin Layer Chromatography.

DCM extract of *S. indicus* flower head showed significant activity against battery of microorganisms. MIC was found to be in the range of 60-120 mmg. Bioautographic studies revealed the presence of an active compound. The extract also showed good cytotoxic activity against all the three cell lines tested with an IC_{50} of 40-55 mmg/ml. Subsequent fractionation and further investigation is underway to isolate the constituent/s responsible for these activsities.

C_{25} *In-vitro* antihepatotoxic activity of combined extracts of *eclipta alba, Andrographis paniculata* and *Picrorrhiza kurroa*

N. Mahadevan*, N. Harish Babu, P. Vijayan, M.J. Nanjan and B. Suresh

J.S.S College of Pharmacy, Ootacamund 643 001

Eclipta alba, Andrographis paniculata and *Picrorrhiza kurroa,* are widely used in many parts of India to treat liver diseases. The aerial parts of *Eclipta alba,* and *Andrographis paniculata* and rhizomes of *Picrorrhiza kurroa* were reported to have hepatoprotective activity. In vitro studies were performed on freshly isolated rat hepatocytes against antitubercular drugs induced hepatotoxicity. The combination of extracts is selected in such a manner to have varied mechanism of actions such as cholestatic effect, antioxidant property, and modulatory property. 95% ethanol extract of aerial parts of *Eclipta alba,* 70% ethanol extract of aerial parts of *Andrographis paniculata* and 95% ethanol extract of rhizomes of *Picrorrhiza kurroa* were prepared by maceration. The dried extracts were standardized for their bitter constituents and subjected for in vitro antihepatotoxicity screening. In vitro studies were performed using freshly isolated rat hepatocytes. The cytotoxicity of antitubercular drugs (hepatotoxicant) was first determined on established cell line and the same concentration was used to study the antihepatotoxic activity of combined plant extracts on the freshly isolated rat hepatocytes. Biochemical parameters reflecting liver function, such as SGOT, SGPT, ALP, LDH, triglyceride, cholesterol, total protein, albumin, total bilirubin and direct bilirubin have been determined. Combined plant extract, ranging from 1000-125 mg/ml and toxicant (500 mg/ml) were selected to screen the hepatoprotective activity. The percentage protection of the combined plant extract was determined by MTT assay. All the treated groups showed protection when compared to the toxicant control. Maximum protection was shown by plant extract at 1000 mg/ml, which was comparable to the protection shown by silymarin at 250 mg/ml. Minimum protection was shown by plant extract at 125 mg/ml.

C26 Analysis of volatile constitutents of *Coleus amboinicus* leaf oil by capillary gas chromatography / mass spectrometry

K. Mangathayaru, Pratik S. Patel*, D. Thirumurgan, D.V.V. Pratap, Dixon J. David, J. Karthikeyan, J. Vasantha

Sri Ramachandra College of Pharmacy, S R M C & R I (DU), Porur, Chennai 600 116

Coleus amboinicus Lour (Labiatae), commonly called 'country borage' is a perennial herb found wild and cultivated throughout India. Owing to its powerful aromatic carminative properties, the leaf juice is used in digestive disorders in children and is indicated in asthma and chronic cough. Leaf essential oil is reportedly antibacterial and weakly herbicidal. Previous phytochemical investigations revealed the presence of vitamins B_1, B_2, B_5 and C, flavonoids - chrysoeriol, apigenin, cirsimaritin, eriodictyl, luteolin, quercetin and taxifolin, triterpenes - euscaphic acid, maslinic acid, oleanolic acid, pomolic acid, tormentic acid and ursolic acid. Leaf essential oil is rich in thymol. The present work reports the GC-MS, analysis of the essential oil of *Coleus amboinicus* as no reports are available on the essential oil components of the plant of Indian origin.

200 g of fresh leaves when subjected to hydrodistillation on a clevenger-type apparatus yielded a highly viscous golden yellow coloured volatile oil (0.24%). It is highly soluble in 80% alcohol and diethyl ether. The physical parameters are $[d]^{25} = 0.934$, $[n]_D^{25} = 1.522$, $[\alpha]_D^{25} = -4°C$, TLC of the oil on Silica gel G using Toluene : Ethyl acetate (93:7) as solvent system revealed the presence of 3 spots of R_f 0.62, 0.73 and 0.95.

GC-MS analysis was performed on a model QP 5000 Shimadzu GC-MS system. The 70 eV mass spectra upon matching with Wiley MS data library and with standard published data resulted in the identification of 10 compounds constituting 95% of the oil sample. Carvacrol (50.67%), γ-Caryophyllene (13.1%) and Patchoulane (8.75%) were the major components. As earlier reports indicate the predominance of thymol, this report suggests the possible existence of chemical races within *Coleus amboinicus*.

C27 Studies on *onosma Bracteatum* wall. mucilage

Vijay D. Gulkari* and K. S. Laddha

A large number of phytoconstituents or their derivatives derived from the plants have been used for therapeutic purposes. Besides, plants are also the major sources for excipients which are required to formulate the drugs into suitable dosage forms. Among the various excipients, gums and mucilages are widely used as pharmaceutical aid for stabilizing the dosage forms. Many plants produce gums and mucilages, some of which are already in use. Considering the importance of mucilages, the present work had undertaken to study the mucilage from the leaves of *Onosma bracteatum* Wall. (Family: Boraginaceae). The present research work comprises of:

1. The collection and identification of the plant material.
2. Extraction of the mucilage.
3. Studies on the mucilage.

Mucilage from Onosma bracteatum Wal. Was isolated by maceration technique using water as solvent and precipitated by the addition of methanol, used as non solvent. The percentage yield from the selected source was 6.44% w/w. Physical characteristic of mucilage such as solubility, swelling Index, loss on drying, moisture content, and pH were studied. Chemical studies such as hydrolysis, oxidation, and methylation were carried out. On acid hydrolysis rhamnose as one of the sugar was identified by TLC and HPTLC. Periodate oxidation of mucilage shows nature and proportion of the glycosidic linkages present in the polysaccharides. One of the important methods of structural determination and the point of union between in different sugar residues of polysaccharides is the methylation analysis.

C29 Phytochemical investigation and pharmacological evaluation of leaves of *Spilanthes acmella,* Murr. for immunomodulatory activity

V.I. Hukkeri., R.V.Savadi*., Kusum.S.Akki., Rajesh yadav., K.P.Manohara and Anilkumar

Department of Pharmacognosy and Phytochemistry.

K.L.E'S College of Pharmacy, Vidyanagar. Hubli – 580 031. Karnataka. India.

Spilanthes acmella, Murr commonly known as akarkara belongs to the family

Compositae, is an annual hairy herb, up to 32-60cm tall with numerous stem and marigold eye flowers. Stem glandular and hairy with pungent taste. Traditionally leaves were used for toothache, rheumatism, diuretic, tonic, adaptogenic and immunomodulatory activities.

Phytochemical investigation of leaves reveals that, it contains alkaloids, carbohydrates, tannins, fats, steroids and carotenoids.

- Immunomodulatory activity was carried out for total ethanolic extract using following parameters

- Modulation of Macrophage function
  - Morphometric and Functional changes in mice
  - Carbon clearance assay in Mice
- Evaluation of Immunopotentiating effect with the help of Cyclophospnamide induced in rats.
- Evaluation of Immunopropylactic effect with the help of E.Coli induced in Mice.
- Immunostimulant activity carried out by the
  - Neutrophil adhesion test.
  - Haemaglutinating antibody (H.A.) titre.

  Delayed type Hypersensitivity (DTH) response in rats.

The results revel that the ethanolic extract of the leaves of *Spilanthes acmella,* Murr. *Possesses* significant immunomodulatory activity.

The observation of the present study scientifically validates its immunomodulatory activity as claimed by traditional system of medicine.

C_{30} Phytochemical and pharmacological investigation on stem-bark of *Helicteres isova* Linn

Badgujar V.B.*[1], Pal S.C.[2], Jain P.S.[1]

R.C. Patel College of Pharmacy, Shirpur (M.S.)[1]

N.D.M.V.P.S. College of Pharmacy, Nashik (M.S.)[2]

Helicteres isora Linn Family : *Sterculiaceae* is a sub-deciduous shrub or small tree. It occurs throughout India. Nepal and Andaman islands. The plant was collected from Anjaneri (Nashik) and was identified by Department of Botany, K.T.H.M. College, Nashik.

The plant material was cleaned, dried and successively extracted by petroleum ether 60-80°C and methanol using Soxhlet apparants. It was found that extract showed presence of steroids, glycosides, sugars, tannins and flavonoids. Two compound β-carotene and β-sitosterol were isolated from petroleum ether extract and were confirmed by spectroscopic techniques such as Co-T.L.C., U.V., F.T.I.R. and N.M.R. whereas some flavonoids were isolated from methanolic extract.

In Pharmacological investigation, the analgesic activity of both extract were tested, it was found that methanolic extract showed 41.26% and 38.75% analgesia for Hot plate method and Writing method respectively.

Both extract were found to be effective against gram negative and gram positive bacteria and also showed prominent activity against pathogenic fungi. In both cases methanolic extract was found to be significant in activity.

C_{31} Screening of antioxidant and antimicrobial activities of Indian marine algae

Gaurav Saxena*, Salma Jhanam and Solimabi Wahidulla

Department of Pharmacognosy Alameen College of Pharmacy, Bangalore and [2]National Institute of Oceanography, Goa.

Marine algae are large and diverse group of photosynthetic organisms that live in oceans and brackish water. They are morphically diverse ranging from microcellular algae to macroscopic algae (seaweeds). The potential biological effects has prompted increased use of seaweeds in manufacturing raw semi-processed products in food industry. The marine algae known to contain polyphenols which are potent antioxidants. The present study reports the antioxidant and antimicrobial activities of butanolic and aqueous extracts of two Indian algae *Sargassum icrerrimium* and *Catderpa sertularcides*. The antioxidant activity was tested using DPPH and FRAP assay. The antimicrobial study was conducted against five microbes namely *Staphylococcus aureus, S epididermis, E.coli, Klebsiella pneumoinae* and *Bacillus Subtilis* using gentamicin as standard. Both the algae were round to possess antioxidant activity at 5 mg/ml concentration. Comparative analyis indicated butanolic extract of *Sargassam* to be potent antioxidant. All the extracts were found to be good antimicrobial agents at a concentration of of 100 mg/ml. Results of antimicrobial screening also proves butanolic fraction of *Sargassam* to be better than other fractions. Hence it can be concluded that the marine algal extracts have good antioxidant and antimicrobial properties which can be commercially utilized in food and cosmetics preparations.

C_{32} Evaluation of herbal drugs for antiacne activity

In our present study we have tried to focus on activity o fcertain plant drugs and volatile oils. Methanolic extracts of *Coscinium fenestratum, Quercus infectoria, Camellia sinensis and oils of Melaleuca alternifolia, Rosamarinus officanalis, Oscimum gratissimum* and *Lavendula officinale,* were tested against gram +ve microaerophilic bacterium known as *Propionibacterium acnes* and aerobic gram +ve Bacteria *Staphylococcus epidermidis.*

The crude drugs of *Coscinium fenestratum Quercus infectroia* and *Camellia sinensis* were collected from the local market and authenticated by Dr. Yoganarshiman Regional Research Institute of Ayurveda, Bangalore. Essential oils of *Melaleuca alternifolia, Rosamarinus officinalis, Oscimum gratissimim* and *Lavendula officinale* were kindly gifted

by Dr. A.A. farooqui, Department of Horticulture, University of Agriculture Sciences, Bangalore.

The crude drugs were dried under shade and powdered. The weighted drugs 9200 gms) were subjected to successive solvent extraction with petroleum ether, chloroform and methanol and concentrated under reduced rpessure.

Staphylococcus epidermidis MTCC 435 and *Propionibacterium acnes* MTCC 1951 were obtained from Microbial type culture collection and gene bank,Chandigarh and maintained at Department of Diagnostic Bacteriology and Mycology, IAH & VB.

Nutrient agar and Nutrient broth were used for cup plate method and broth dilution method for testing antibacterial activity of methanolic extracts and essential oils as described by Janssen et. al (1987).

Propionibacterium acnes cultures were maintaind using Rabbit blood agar medium in anaerobic conditions and MIC of the drugs were determined using Nutrient yeast extract glucose broth by broth dilution method described by Bailey and Scot (1991).

All the seven samples were found to be active against acne causing bacteria. The zone of inhibition was found to be in the range of 18-22 mm at the concentration of 10 mg / ml for *S.epidermidis,* while MIC was found to be between 500-1000 µg/ml for methanolic extracts and 1/200-1/400 for volatiles oils. MIC of various extracts against P.acnes was found to be between 1/100-1/300 dilution of essential in DMSO. These results suggests good potential of these drugs in preparation of antiance formulation.

The tested drugs can be formulated and evaluated for antiance formulation consisting or single drugs or a comibation of drugs.

C_{33} Extraction, isolation and structure elucidation of a new phytosterol from *Asparagus racemosus* root

K. Zaman*, M. Ali**

*Dept. of Pharmaceutical Sciences. Dibrugarh University, Dibrugarh.

** Faculty of Pharmacy, Jamia Hamdard, New Delhi 62

A new phytosterol has been isolated from the roots of *Asparagus racemosus*, a climbing under shrub, whose roots are used as an important component in several Ayurvedic and Unani medicinal preparations for its galactogogue, adaptogenic and aphrodisiac properties. The phytosterol extracted from the roots of the plant followed by isolation and purification is obtained as colourless crystalline compound.

The new phytosterol is established to be Stigmast, 5, 22-diene-3α-ol (molecular formula- C_2-$H_{48}O$ with melting point - 102 - 104°C has been named as asparagusterol. The present communication describes the extraction, isolation and structure elucidation of the new phytosterol obtained from the *Asparagus racemosus.*

C_{34} Marker based standardization of zuroor-E-Qula : a polyherbal formulation

Paridhavi M*, Agrawal S.S.

Delhi College of Pharmacy, Pushp Vihar, New Delhi

Zuroor-e-Qula is one of the traditional polyherbal formulation used as anti-microbial and anti-inflammatory drug. It contains[1] mixtures of various powdered ingredients like *kathsafaid (Acacia leucopholoea), tabasheer (Bambusa bambos), kafoor (Cinnamomum camphora), dana heel khurd (Elettaria cardamomum), gulnarfarsi (Punica granatum) gul-e-surkh (Rosa Damascenena), kabba-e-khandan (Zanthoxylum armatum).* The polyherbal formulations can be standardized based on its Organoleptic, macroscopic microscopic, biological properties and also upon the nature of the chemical constituents it contains. **Marker** is the compound used as a reference for standardizing the test material. The markers can serve a means of measurements in establishing the identity of individual drugs of the polyherbal formulation[1]. Thus chemical markers play a significant role in the quality control of polyherbal formulations, to minimize the bath variability, to check the content uniformity.

The selective, sensitive, precise, accurate and reproducible analytical techniques must be considered for the polyherbal formulation.

The alcoholic extract of the PHF was shown 7 spots in toluene: ethyl acetate: ethanol (3:3:4) upon treatment with 5-10% ethanolic Sulphuric acid followed by heating at 105°C for 45 min. These seven spots were correlated with the **co-chromatography** of isolated marker compounds. The chromatogram properties were as follows. Compound 1 (PHF7spots at Rf 0.12, 0.15, 0.24, 0.33, 0.51, 0.66 and 0.83); compound 2(0.12, darkbrown), compound 3(0.15 pink), compound 4 (0.24 lightbrown), compound 5(0.33 brown), compound 6 (0.51, light red to brown), compound 7 (0.66, light red to white) and compound 8 (0.83, brownish blue).

The **fixed oil** was isolated from the formulation by solvent extraction method (petroleum ether) and the **volatile oil** was isolated by hydro-distillation method and was analyzed by **GLC** and **GC-MS** studies. The details of the structure of the interpreted compounds will be shown at the time of presentation.

C35 Study of hepatoprotective activity of fruit extract of melanoxylon

P.K. Sahoo

AICTE, New Delhi

Herbal preparations were the most ancient to be used in the treatment of various disease in the Indian System of medicine. Plants, animal and mineral products are important constituent of Ayurvedic medicine. A number of such herbal preparations have got protective effect against disease process and chemical injury to various organs including liver. The modern scientist have worked on different plants and their constituents and proved them to be beneficial in case of liver disorders.

With the advent of allopathic system the indifenous system was ignored. With realization of the severe side effects, which could be either acute or chronic, medical methods over the world now prefer to go back to natural drugs. In fact even the allopathic system contains drugs derived from natural resources. There are certain ailments, which have no answer in allopathic system of medication but could be cured in indigenous system. The ailment, arthritis, some forms of skin diseases, chronic fevers, diabetics, liver disease etc. The answer while searching for such plants are useful in liver disorders has come across the plant *Diospyros mealnoxylon* and was taken up for a study of its usefulness as a hepatoprotective.

Hepatoprotective activity of various extracts of leaf, bark and roots of various plant proved to be effective in protective the liver from hepatotoxic substances. Many of them also found to accelerate the process of regeneration and recovery of the hepatocytes damage various offending agents.

In India a number of Ayurvedic preparations are used for the liver ailments. Some indigenous herbs like *Phyllanthes niruri, Ricinus communis, Eclipta alba, Aloes.A. calanus, Menatha piperita, Tephrosia and Boerhhavia, Picrorhiza* species are used in preparations.

In the present study the author has taken up the fruit extract of *Diospyros melanoxylon* and studied its hepatoprotective activity against carbon tetrachloride induced hepatotoxicity. The author has taken up this plant for study, from some of his observation of the use of the different parts of this plant by the local folklore. The Serum Glutamate - Oxaloacetate Transaminase (SGOT) and Serum Glutamate Pyruvate Transaminase (SGPT) and Alkline Phospatase (ALKP)bilirubin level increased in CCl_4 induced hepatotoxicity. The results of SGOP, SGPT, and bilirub in level after adminsitration of the plant extract have been found to bringdown SGPT, SGOT, SLKP and bilirubin level to the normal. The plant extract shows definite roll for hepatoprotective activity.

C36 Wound healing activity of the leaves of *Artocarpus heterophyllus* Lam. (Jackfruit)

V. S. Joshi[a], K. S. Patil[b], N. S. Vyawahare*[a], N. T. Gharge[a]

AISSMS College of Pharmacy, Kennedy Road, Pune411 001, KLES College of Pharmacy, Belgaum

Jack tree is a large, evergreen tree, 10-15 m in height, indigenous to the evergreen forests of the western ghats of India, at an altitudes of 450-1, 200 m and cultivated throughout the hotter parts of India[1]. The young leaves as fomentation are applied to boils and wounds to dry them[2]. A survey of literature showed that antibacterial activity[3] had been carried out on the leaves of *A.heterophyllus Lam* and found significant.

To study the wound healing activity of the leaves of artocarpus heterophyllus on albino rats. The leaves of *Artocarpus heterophyllus* Lam. (Jackfruit) were dried and extracted with different seven solvents with increasing polarity. The different extracts were studies for Wound Healing property on Albino Rats. The parameters used were Incision Wound, Granuloma (Dead space Wound) Studies, Excision Wound Model. The Wound Healing activity was compared with the standard. The doses of various extracts were determined by the graphical method of Miller and Tainter.

In the Incision Wound Model methanolic extract showed increased tensile strength (213.25 + 12.90) Followed by butanone extract (200.25 + 19.12), thus more significant.

In the granuloma studies methanolic extract showed increased tensile strength (248.00 + 5.05) Followed by butanol extract (210.83 + 8.63), thus more significant.

In excision wound model percentage wound closure was checked on the 4th, 8th, 12th, 16th post wounding day, Methanolic extract was found more significant.

All the extracts were found to have wound healing activity. Methanol & butanol extracts had shown better wound healing activity, but Methanolic extract was more significant. This property may be due to flavonoid present in it, as this has a reference of the flavones of *A.heteophyllus* showing antibacterial activity.

D1 Studies on evaluation of *in-vitro* antimicrobial potential of bark of *lagerstroemia parviflora* (Roxb)

Avijit Mazumder[1*], Rupa Mazumder[1], S.P. Basu[2], B.P. Saha[3]

1. Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi – 835 215, India.
2. Seemanta Institute of Pharmacetical Sciences, Jharpokara, Mayurbhanj - 757 087, India
3. Department of Pharmceutical Technology, Jadavpur University, Kolkata – 700 032, India

Depending on the traditional uses of various parts of *Largerstroemia parviflora* Roxb. (*Lythraceae*), the methanolic extract of the bark was investigated for its invitro antimicrobial potential. The minimum inhibitory concentration (MIC) of the extract was determined by agar dilution technique against 15 different strains belonging to nine different genera viz., *Staphylococcus aureus, Bacillus spp., Lactobacillus arabinosus, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Shigella spp., Sarcina lutea and Vibrio cholerae.* Further, the antibacterial activity of the extract was assayed by disc diffusion method against few selected microorganisms. The diameter of zone of inhibition was compared with that produced by a standard antibacterial agent, ciprofloxacin. It can be concluded that the extract is active against both gram positive and gram negative microorganism. Alkaloid, tannin and triterpenoids are present as phytochemical constituents in the extract. Our findings confirm the traditional folklore claim of this plant. The bark extract is proved to be bactericidal in nature. We are sure that the bark extract of *Lagerstroemia parviflora* will be able to replace the conventional antimicrobial agents to which the microbes are generally showing high resistance resulting in the global threat of drug resistance. Further, experiments regarding invivo antimicrobial study and isolation of chemical compounds responsible for the antibacterial activity are under way.

D2 Search of cox-II inhibitors from natural sources

B.N. Sinha*, S. Vadivelan, Manik**

Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi – 835 215.

India has a very rich flora and fauna due to its unique climatic condition and several plants have been used for variety of clinical conditions in the traditional and folklore medicines. *Spermacoce articularis* Linn of the family *Rubiaceae* (syn. *Spermacoceae*) is one such plant which has been used in traditional systems of medicine for number of clinical conditions. The plant has been least explored as per literature reviewed from 1907 till date.

The present study involves phytochemical, pharmacological, molecular modeling and docking studies. The dried plant material was extracted successively with solvents of increasing polarity. All the extracts were subjected to phytochemical screening, which revealed the presence of sterols, terpenoids, flavonoids and some phenolic compounds. The extracts were further processed to afford five pure compounds viz. Compound I, Compound II, Compound III, Compound IV and Compound V.

Pharmacological screening revealed the anti-inflammatory activity of this plant. Its benzene extract at a dose of 150mg/kg body weight produced 76% inhibition of oedema induced by carrageenan in hind paw of rats.

The molecular modeling and in-silico screening of phytoconstituents were also done for selectivity of COX – I and COX – II receptors.

D3 Evaluation of adaptogenic activity of grape seed extract (GSE) employing biochemical approach in rats

S. Satyanarayana, B. Krishna Murthy*, N. Srinivas and K. Sushruta

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam – 530 003.

Stress is a subject, which is hard to avoid. Anything that causes a change in life causes stress. The stress leads to several disorders like common cold, headache, cancer, bronchial asthma, heart attack, anxiety, neurosis, gastric ulcers, constipation, spastic colon etc. In Ayurvedic system of medicine it is claimed that stress can be controlled with Grape Seed Extract. The objective of our study is to provide scientific support for the claim.

Since stress increases the release of catecholamines and also involves hypothalamo pituitary – adrenal axis, the urinary levels of vanillyl mandelic acid (VMA) a metabolite of catecholamines and ascorbic acid (AA) a product of adrenal system were taken as indirect indices in rats to evaluate the anti-stress effect of Grape Seed Extract.

The rats of either sex weighing between 120 to 150 gm. are divided into four groups. (I, II, III, IV) each containing five. In the first phase of the experiment, the urine samples were collected from all the four groups at 24 hr intervals daily for 7 consecutive days. In the second phase the group I was treated as control and groups II, III, IV were administered with

Grape Seed Extract orally at doses of 100, 200, 300 mg/kg body wt. respectively. In the third phase of the experiment all the four groups were subjected to stress by fresh water swimming for 3 to 4 minutes for seven consecutive days and the 24 hr urine samples were collected. In the final phase of study, Group II, III & IV administered with 100, 200, 300 mg/kg body wt. of Grape Seed Extract one hour before applying the stress and in all the cases urinary levels of VMA & AA were determined in 24 hr samples.

The VMA & AA were fairly constant in control condition. (VMA 197.5 mg/24hr/ 100gm body weight, AA 141.3 mg/24hr/ 100gm body weight). There was no change in VMA and ascorbic acid levels when Grape Seed Extract was administered to normal rats indicating that it does not interfere with basal levels. The swim stress increased urinary VMA from 197.5 to 381.55 mg/24hr/ 100gm body weight and decreased ascorbic acid from 141.3 to 80.3 mg/24hr/ 100gm body weight. The changes in VMA & AA were antagnozed with prior treatment with Grape Seed Extract and the effect was dose dependent. It also produced hydroxyl radical scavenging activity in in-vitro system conducted separately. The in-vitro results and in vivo biochemical changes against swim stress provide evidence for its anti stress (adaptogenic) activity in rats.

D_4 Scientific investigation of secret warfare practices in Kautilya arthashastra

Nandakumar K[a], Soumya Ghosha, Apt AA[a*], Bhavasar SN[a], Bodhankar SLb, Gore Mc and Jagdale Rd, Ghole V S[a].,

a. Department of Environmental Sciences, University of Pune, Ganeshkind, Pune – 411 007.

b. Department of Pharmacology, Bharati Vidyapeeth Deemed University, Poona College of Pharmacy, Erandwane, Pune – 411 038.

c. National Institute of Virology, Pune.

d. Science and Technology Park, University of Pune, Pune- 411 007.

Rats were treated orally with formulation 600mg/kg (or vehicle) for 14 days. Daily food intake was noted for the first 7 days from 8th day the rats were starved till 14th day. Body weight, rectal temperature, motor activity, and presence of ketone bodies in urine, was recorded daily during the starvation period. Blood samples were collected on 8th, 11th and 14th day and estimated for Glucose, cholesterol, urea, albumin and total protein in serum.

Formulation I (600mg/kg) did not affect the food consumption and motor activity however it was able to maintain body weight glucose and cholesterol level significantly higher than the control group on day 14th. Ketone bodies were absent in control group but were present in treated group suggesting delayed fat metabolism. About 46% animals died in control group while 92% animals survived in treated group.

Formulation I (600mg/kg) delayed carbohydrate, lipid and protein metabolism in a conserved manner enabling the animal to sustain for a longer period of time as compared to control group.

D_5 Development of hollow balls of *P. ovata* and study of synergistic action of aloe vera in combination

A.P. Mehere, V.H. Bankar, M.M. Bankar

70, Sujata Layout, Dindagal Nagar, Nagpur

Using standardised *P. ovata* powder and Aloe-vera gel, hollow balls were prepared and evaluated for following parameters, hardness, uniformity of weights, loss of drying, friability, viscosity, in vitro displacement of balls, volume of balls, water absorption gel strength etc. The balls satisfies the bulk laxative property in a synergestic way and also have shown increased displacement of bowel. It do not adhere to mouth cavity and can be easily swallowed.

D_6 Evaluation of polyherbal formulation in experimentally induced gastric ulcers in rats

K. Elango, Sujith H. Dass, T Subburaju[1], Girish S. Parhate* and B. Suresh

1. Department of Pharmacognosy, J.S.S.College of Pharmacy, Ootacamund, Tamilnadu-643001.

The anti-gastric ulcer study of the poly herbal formulation -from the 50% Ethanolic extract of rhizomes of *Glycyrrhiza glabra*, leaves of *Coccinia indica.*, whole plant of Solanum nigrum, "Bhasma" from the fruit of *Musa paradisiaca* and "Pirandai uppu" from whole plant of *Cissus quadrangularis*, showed significant activity at a dose of 200mg/kg, as deduced from the ulcer index of all the four models viz., modified pylorous ligated (Shay) rat model, Aspirin plus pylorous ligated (Shay) rat model, Ethanol induced acute gastric mucosal lesions in rats and Acetic acid induced chronic gastric ulcers in rats.

From the biochemical estimations Viz., i)Carbohydrate content Flucose, Sialic acid, hexosamine, total hexose and total carbohydrates, showed significant alteration for the anti- ulcer activity. (ii) Secretions of enzymes - pepsin, total proteins, free and total Acidity, pH, and gastric volume, showed significant anti-ulcer activity. (iii) Gastric mucosal defense factor like estimation of mucosal barrier and Antioxidant enzymes like Catalase, Superoxide-dismutase, glutathione, Lipid peroxidase were significantly altered. From the histopathological studies it showed a

significant alteration in support of anti-ulcer activity. From all the above results it has been observed that the polyherbal formulation has dose dependent activity and it was significant at a dose of 200mg/kg. The formulation has shown the comparable activity with positive control as ranitidine (27mg/kg) for antisecretory activity and with Sucralfate (270mg/kg) for cytoprotective activity.

D_7 In-vitro and in-vivo antioxidant potential of *lactuca sativa* - A prospective nutraceutical

Munish Garg*, Chanchal Garg, Pulok K. Mukherjee, S. Badami & B.Suresh.

J.S.S. College of Pharmacy, Ooty (Tamilnadu) – 653001.

The present study is based on the evaluation of antioxidant potential of a well known plant *Lactuca sativa*. Methanolic leaf extract of the plant was investigated for in vitro effect of oxidative damage induced by UV-radiations to the *Salmonella typhi* bacteria and in vivo effect on the production of body enzymes i.e. catalase and superoxide dismutase.The measurement was also done on the production of lipid peroxidation in terms of thiobarbituric acid reactive substances in blood and brain of male albino wistar rats.

The plant extract incorporated sample has shown significant antioxidant potential by inhibiting the oxidative damage caused by UV-radiations resulting in increased number of colonies as compare to the control. The plant extract has also shown good activity by increasing the catalase and superoxide dismutase production in the blood and brain of experimental animals at different extents. The extract has also reduced the lipid peroxidation significantly. This confirms the antioxidant potential of plant both in vivo and in vitro.

D_8 Standardization of poly herbal cough sryup by high performance thin layer chromatography

D. Prasanna*, B. Samuel Thavamani, F.E. Solomon, G.K. Sivaraman

M/s. apex laboratories limited

India is the home to traditional medical practice for over 2000 years. The main branches of Indian system of medicines are Ayurveda and Siddha. Unfortunately the authenticity of this system is not well developed due to commercial exploitation and entry of many spurious products. Hence the genuine manufactures are in need of proper scientific backing and support to enable the creative progress of this system. This paper aims to standardize the raw materials and finished products used in the formulation of poly herbal cough syrup. It contains the herbs like *Bryonia scabrilla, Coleus aromaticus, Barleria prionitis, Piper longum, Alpinia chinensis* etc.,

We have developed a simple and precise method for the analysis of individual raw materials and finished products of our herbal cough syrup using High Performance Thin Layer Chromatography.

Excellent peaks were obtained for all the raw materials as well as finished products. The important thing to bear in mind is that the chromatographic conditions should be most probably ideal to get a good response. Ideal chromatographic conditions and similar finger print pattern of both the sample and standard drugs (in-house specification) suggest the presence of similar active principles present. HPTLC studies proves the scientific and sophisticated method of detecting the adulterant / substitute in the raw materials. In order to expect the desired therapeutic effect of the drugs it is essential that scientific quality parameters accepted by WHO have to be evolved for all the herbal drugs to check the purity, identity, efficacy and detect the adulterant / substiuent.

D_9 Standardisation of dianex an antidiabetic formulation by high performance thin layer chromatography (HPTLC)

B. Samuel Thavamani*, F.E. Solomon, Prasanna, G.K. Sivaraman.

M/s. Apex Laboratories Limited

Dianex is an antidiabetic poly herbal formulation supported by well-controlled preclinical, clinical trials and toxicity studies. This work aims to standardize the formulation by chromatographic fingerprinting. This formulation contains herbs like *Gymnema sylvestre, Momordica charantia, Eugenia jambolana, Aegle marmelos, Withania somnifera* etc.,

Maintaining the same Physico-Chemical proportions of a product in all through the process of preparation and utilization leading to identical therapeutic efficacy in all batches is called standardization. When the medicines were fingerprinted and interpreted the chemical and therapeutic quality are be correlated. We have developed HPTLC analytical methods for our Dianex formulation and each ingredient of the formulation.

Although some of the plants used in this formulation are covered in various Pharmacopiea, their standards especially in terms of chemical markers and TLC finger printing have not been covered. Therefore we have taken maximum efforts to create in-house specification for Dianex formulation and each plant extracts involved in it.

HPTLC instrument analysis provides not only flexible screening procedures and qualitative analysis, but also for demanding quantitative determinations. This instrument can be easily validated and is fully compliant with GLP.

If we standardize all the herbal formulations using modern techniques, definitely there will be a promising future for traditional medicines world wide along with other modern therapies.

D_{10} General protocol for herbal drugs standardisation

R. Kamaraj', Janani. K*, Janani. S and A. Amalraj

College of Pharmacy, Sri Ramachandra Medical College & Research Institute (DU), Porur, Chennai 116

Herbal drug standardisation has become the major priority among pharmaceutical can enter global market. Herbal standardisation involve various aspects of cultivation analysis, formulation design, phytochemical assay, Bioefficacy studies, toxicity studies, quality control and clinical research. This process includes producing products which are stable on packing, high speed of release of active constituents. Various aspects of consumer preference, commercial factor, modern technology, cost and more appropriately selection of a herbal drug for a formulation. It also becomes important to assure the quality of the standardised herbal drug formulation, where by the formulation can easily capture the global market. Thus it is necessary to ensure the synchronised functioning of all the above mentioned factor to bring about a standard product. Hence a general protocol which states the standards for standardisation of herbal formulations has becomes indespensable for herbal industry in the global market.

D_{11} Hepatoprotective and free radical scavenging activity of *Terminelia belerica*

Patel N. M.[1]*, Patel P. M.[2], Patel V. P.[1], Patel J. L[3]., K. Pundrikakshudu[3] & Bhavsar G. C.[3]

Terminelia belerica (Combretaceae) is claim as the medicinal potential in Ayurveda. Hence it was included in our scheme of investigations for antihepatotoxic and antioxidant activities. Generation of excess of peroxidase enzymes, which produce free radicals and trigger a cascading reaction. Hence it was felt rather logical to correlate the antihepatotoxic activity with antioxidant activity.

Methanolic extracts of *Terminelia belerica* were studied in CCl_4 induced hepatic damage in rat. Silymarin (25 mg/kg.) was used as reference standard. Significant change in SGOT, SGPT, ALP, bilirubin, and total protein level were measured. Histopathology was carried out for confirmation. Antioxidant activity was studied by DPPH, Nitric oxide scavenging, and super oxide methods.

The reduction in the level of SGOT, SGPT and ALP after administration of methanolic extract of *T. belerica* (300mg/kg) was significant. EC50 values were find out for DPPH, Nitric oxide scavenging, and super oxide methods. These results show *C. procera* having hepatoprotective and antioxidant activity. The results were confirmed by histopathological study.

D_{12} Hypoglycaemic and antidiabetic activities of gmelina arborea stem extract in rats.

S. Satyanarayana, P. Ram Mohan and A. Ramesh*

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam, A.P. India-530 003.

Diabetes mellitus is a metabolic disorder characterized by high blood glucose level. The objective of our study is to evaluate the ethylacetate extract of *Gmelina arborea* (GMA) stem for its hypoglycaemic and antidiabetic activities since it has been widely used by tribal people to treat diabetes.

Different doses of GMA extract 30, 100 and 300 mg/kg body wt. were tested on normal rats and alloxan induced diabetic rats(110-160 gm). Group-I served as control and were administered orally with vehicle dimethylsulfoxide (DMSO) at a dose of 3 ml/kg body wt. G II, G III, G IV were administered orally 30, 100 and 300 mg /kg body wt. of GMA in DMSO. Similar studies were conducted in alloxan (100-120mg/kg) induced diabetic rats with 100 and 300 mg/kg body weight doses of the extract. Blood samples were collected from retro-orbital puncture at 0, 2, 4 and 6 hr intervals and were analyzed for glucose by GOD/POD method using commercially available glucose kits.

In normal rats GMA extract reduced blood glucose level by 6.38% and 21.06% with doses of 100 & 300 mg/ kg body weight respectively at 4 hr. Elevation of blood glucose level by 21.87% was seen at 4 hr with dose of 30 mg/kg body wt. In control group (DMSO treated) the blood glucose level was elevated by 36.10% at 4 hr.

In Alloxan induced diabetic rats GMA extract reduced blood glucose level by 10.35% and 30.79% at 4 hr. with doses of 100 and 300 mg/kg body wt. respectively. In control (DMSO treated) the blood glucose level was elevated by 37.96%. The results indicate that at doses 100 and 300 mg/kg body wt. of GMA, the extract produced approx 10% & 30% reduction indicating that the extract worked against the hyperglycemia produced by the combined effect of

Alloxan & DMSO. The study also indicated that DMSO oral dosing can be used as an acute model to produce hyperglycemia in rats.

D13 Standardisation and formulation development and hard gelatin capsules for liveral - a hepatoprotective formulation

F.E. Solomon*, B. Samuel Thavamani, D. Prasanna, G.K. Sivaraman

M/s. apex laboratories limited

The aim of this work was to formulate a physically and chemically stable hard gelatin capsule formulation for a standardized herbal recipe. The formulation contained a combination of herbal powders viz. *Phyllanthus niruri, Eclipta alba, Boerhaavia diffusa, tinospora cordifolia, Tribulus terrestris, Tephrosia purpurea, Indigofera tinctoria, Aconitum heterophyllum, Andrographis paniculata, Rubia cordifolia, Terminalia chebula and Curcuma longa*. The active principles of these herbal powders have been reported to have Hepatoprotective activity. Hence these herbal powders were formulated in the form of capsules for treatment or supportive thereapy for Liver disorders. We have developed HPTLC analytical methods for our herbal formulation Liveral as well as for each ingredient in the formulation.

Each of the powdered dry extract was standardized and the capsules were formulated containing herbal extracts in specific proportions. Various formulations were tried using different lubricants viz. Aerosil, Magnesium stearate, Talc and Starch in appropriate proportions. The capsules were filled using automated capsule filling machine. The powder premixes before filling in the capsules were evaluated based on following parameters : Angle of repose, bulk density, tapped density, flow rate. The formulated capsules were assessed for their suitability by determining parameters such as weight variation and chromatographic fingerprinting. Accelerated stability studies were carried out for appropriate period. No changes in the parameters were observed when subjected to various temperature and humidity conditions.

Thus stable formulation for Herbal powders having Hepatoprotective activity was achieved in the form of capsules and the product was standardized with the help of HPTLC fingerprinting.

D14 Some indian traditional medicinal plants with antioxidant potential : a study

Vivek Kumar[1], Sumitra Singh[2] and Surendra Kr. Sharma[2*]

1. Lord Shiva College of Pharmacy, Sirsa (Haryana)
2. Department of Pharmaceutical Sciences, Guru Jambheshwar University, Hisar (Haryana)

In Ayurveda, Rasayana includes a number of medicinal plants which are used traditionally for thousands of years in herbal preparations for their significant antioxidant activities. In the present paper four plants Amla *(Emblica officinalis : Euphorbiaceae)*, Tulsi *(Ocimum sanctum : Labiatae)*, Mulethi *(Glycyrrhiza glabra : Leguminosae)*, Amarvela *(Cuscuta reflexa : Convolvulaceae)* are viewed for their antioxidant potential. The antioxidant activity of tannoid active principles of *E.officinalis* on the basis of their effects on rat brain frontal cortical and striatal concentrations of the oxidative free radical scavenging enzymes superoxide dimutase (SOD), catalase (CAT) and glutathione peroxidase (GPx), Thiobarbituric acid reactive substances (TBARS) is compared with MAO B inhibitor. An increase in both frontal cortical and striatal SOD, CAT and GPx activity is seen. Antioxidant activity of aqueous extract of *Ocimum sanctum* was studied in adult Swiss mice. Aqueous extract was given intraperitoneally and then exposed the mices to gamma radiation. Pretreatment with the extract checked the radiation induced depletion of GSH and all the enzymes, all the enzymes maintained their levels with in or above the control range. The ethanolic extract of Glycyrrhiza glabra root was evaluated for its wound healing property by incision and excision wound models. The wound healing properties of the extract may be attributed to the antioxidant activity of the extract, which may be due to the flavonoids present in the extract. Apigenin-7-O-glucoside, kaemferol-3-O-α-rhamnoside and myricetin-3-α-rhamnoside have been isolated from the stems of *Cuscuta reflexa*. The antioxidant activity of glycoside was measured by estimating degree of non-enzymatic hemoglobin glycosylation at 440 nm and compared with α-tocopherol and rutin were used as active reference substances, myricetin-3-O-α-rhamnoside showed remarkable antioxidant activities. Antioxidant activity is present due to flavonoid glycosides in *Cuscuta reflexa* and in *E.officinalis* due to the presence of active tannoid principles. Aqueous extract of Ocimum sanctum provides protection against radiation injury and *Glycyrrhiza glabra* root extract shows good wound healing properties. So a polyherbal formulation may be developed by combining the active principles of these herbs for synergetic effects.

D15 Formulation and evaluation of some herbal shampoos

Jaison Varghese, Geetha Rao C.G.*, Ramana M.V., E.V.S. Subrahmanyam, D. Satyanarayana

NGSM Institute Pharm Sciences, 3rd Cross Road, Vivekanand Road, Nanthoor, Mangalore 575 005. Karnataka

The work on "Formulation and Evaluation of Some Herbal Shampoos" was undertaken with the objective of making a completely natural shampoo, using herbal products, so that it possesses ideal qualities of a shampoo such as cleansing and conditioning along with extra qualities like promoting hair growth, antidandruff activity, maintaining hair colour and preventing hair loss. Such a product can be safer than most of the currently available synthetic shampoos, which are alkaline causing hair fall or contain harsh chemicals.

The plants / plant products were chosen to provide the required properties – soapnut, bengalgram and bimbi, as detergents; hibiscus, bimbi, aloe and brahmi as conditioning agents; neem and tulsi as insecticides and preservatives; methi, amla, tulsi as antidandruff agents and amla and eclipta as hair growth promoters and hair colorants.

Aqueous extracts of different raw materials were prepared in different concentrations. The concentration showing the best performance in terms of detergency, conditioning, hair growth and antidandruff activities was selected for each material. Using these concentrations the final formula was developed. An emulsion based product was also formulated with the purpose of improving its properties. These two products were subjected to evaluation tests.

Results indicated that both the products were comparable to marketed brands with respect to detergency. They showed better conditioning, antifungal, antidandruff activities and hair growth promoting qualities especially the emulsion based product. Their acidic pH adds to conditioning effect, preventing dandruff and hair fall. Inclusion of preservatives could be avoided as the products were self preserving.

D16 Hepatoprotective activity of the standardized fruit extract of *Terminalia pallida* against carbon tetra chloride induced liver damage

V. Thamilselvan*, L. Manikandan, G.P. Senthilkumar, P.K. Haldar, S. Bhattacharya, U.K. Mazumder and M. Gupta

Department of Pharmaceutical Technology, Jadavpur University, Kolkata

Terminalia pallida B. (Comberatacea) is a small evergreen endemic tree mainly distributed in Tirupathi hills, Andhrapradesh, India. The fruits of this plant are widely used in the treatment of various ailments such as ulcer, diarrhoea, diabetes and venereal diseases. In Indian traditional system of medicine the fruits of this plant is widely used in the treatment of hepatic disorders. Recently it has been reported that the fruit extract of the plant was found to possess anti-diabetic and anti-microbial property. In the limelight of its traditional use the present investigation was carried out to evaluate the hepatoprotective activity of the standardized fruit extract of *Terminalia pallida* in carbon tetrachloride induced hepatic damage in rats.

Biochemical parameters such as Serum Glutamate pyruvate transaminase (SGPT), Serum Glutamate oxaloacetate transaminase (SGOT), Alkaline Phosphatase (ALP) and total bilirubin were estimated. Glycogen, thiobarbituric acid reactive substances (TBARS) and glutathione levels in liver were also estimated to assess the liver function. Histopathological examination of liver tissue was also performed.

The standardized fruit extract of *Terminalia pallida* at the doses of 250 and 500 mg/kg body weight orally for 16 days restored the altered biochemical parameters when compared with that of the control animals. From the present investigation it can be concluded that the standardized fruit extract of *Terminalia pallida* affords significant protection against CCl_4 induced hepatic damage in rats.

D17 Comparative phytochemical and antidepressant evaluation of *hypericum perforatum* and *hypericum hookerianum* in depressive wistar rats

S. Manimaran, C. Saravana babu*, J. Nirmal, M. Ramanathan, B. Suresh

Department of Phytopharmacy and Phytomedicine TIFAC CORE in HD, J.S.S College of Pharmacy, Ootacamund - 643001, Tamil Nadu.

Hypericum hookerianum, family Hypericaceae, been reported for the hypericin content, hence an attempt was made to have comparative evaluation of percentage of hypericin content and on its antidepressant activity in rats. Hypericin content in *Hypericum hookerianum* and *Hypericum perforatum* was determined by HPTLC technique, which was found to be 0.22% and 0.39% respectively. Chronic unpredictable mild stress (CUMS) protocol was employed to induce depression in rats. *Hypericum hookerianum* showed significant antidepressant activity in Porsolt's swim test, which was comparable with standard drug Imipramine and *Hypericum perforatum*.

Further, it also exhibited anxiolytic activity in open field exploration behaviour and in Actophotometer. It can be concluded that stress produced depression and treatment of *Hypericum hookerianum* significantly reversed the stress induced depression.

D18 Diuretic activity of the ethanolic extract of the leaves of *Nyctanthes arbortristis* Linn.

Sanjita Das*, D. Sasmal, Subrat Kar, Manoj Kumar Biswal

1. Department of Pharmacology, Seemanta Institute of Pharmaceutical Sciences, Jharpokharia-757086,Orissa.*
2. B.I.T., Mesra, Ranchi.

Nyctanthes arbortristis Linn (family : *Oleaceae*) is a common wild hardy large shrub or small tree which is widely used in the traditional medicinal systems of India along with several Pharmacological investigations. Keeping in view of the medicinal importance of this plant and the increasing need of diuretics an effort has been made to establish the diuretic activity of the ethanolic extract of the leaves of *Nyctanthes arbortristis L.*

The shade dried leaves of *Nyctanthes arbortristis L.* were extracted with ethanol(90%) after removing their chlorophyll and fat and then subjected for testing their diuretic activity by following the method of Lipchitz et al. Immediately after dosing, the rats were placed in the specially designed metabolic cages to separate urine and faeces (2 in each cage) deprive of food and water. The urine was collected in measuring cylinders 5hrs. after dosing. The parameters taken were body weight, total urine volume, urine concentration of sodium, potassium, chlorine ion by titration with silver nitrate solution using potassium chromate as indicator.

After statistical analysis it has been found out that the ethanolic extract possesses significant diuretic activity($P<0.01$) which was comparatively less than that of the reference compound frusemide. The extract was found to increase the concentration of cations and anion in urine.

The present study shows that the ethanolic extract of the leaves of *Nyctanthes arbortristis L.* possesses good diuretic activity with significant increase in the cation and anion excretion which was less than the frusemide.

This study may help to understand its less known diuretic effect and to reintroduce confidence amongst their users.

D19 Formulation and clinical evaluation of analgesic tooth powder of roots of *Argemone mexicana* linn.

P.V. Kasture, K.B. Burade, P.V. Kamble*

Govt. College of Pharmacy, Karad

Today almost entire population is facing problems regarding dental diseases. According to survey made by general dental council 99% children under age 12 suffer from dental caries and dental pain, only 20% children below 5 year age have sound teeth. So there is need of dental analgesic which is economic and with minimum side effects. *Argemone mexicana* Linn is a weed, which occurs abundantly throughout India. According to ancient literature and herbal practitioners it has dental analgesic and anti-inflammatory action. It also has antiinfective, anodyne, depurative , sedative actions.

In present work *Argemone mexicana* Linn. root powder (25%) is formulated with other ingredients i.e. precipitated calcium carbonate (70%) , sodium palmitate 5%, flavoring and sweetening agent (q.s.) in preparation of tooth powder. The clinical evaluation of tooth powder for analgesic property was carried out. A group of ten patients with gingivitis and dental pain i.e. toothache were selected. This group is provided with this analgesic tooth powder. Patients instructed to use this powder twice daily they are also suggested not to use any other dental analgesic during study period. Observations for analgesic activity was recorded with patient's experience on tenth day it has proved that, this powder is effective in dental pain i.e. toothache and gingivitis. Thus we can use this herbal medicine with economy, better results and minimum side effects. In recent future this may act as a good alternative for allopathic analgesics. *Argemone mexicana* Linn is available as a weed so weed control can also be achieved.

D20 Need of standardization and evalution of traditional herbal drug

Aashish Sharma*, Anju Goyal, Rahul Garg, Jayesh Dwivedi, Amit Jain and Bharat Vashishta.

B.N. College of pharmacy, Udaipur (Raj.),313001

Man from very beginning has been aware of the problem of life and has been taking care of health through diet and drug for which plants are used extensively. Recently adverse event with herbal supplement in countries such as the US, indicate toward the urgent need for herbal standardization and evaluations.

Main object of standardization and evalutions are

- Quality evalutions and standardization of herbal drugs and their products.
- Scientific validation of ethno botanical claims.
- Development of various herbal formulation based on indigenous and ethno botanical knowledge and their standardization and toxicological evolutions.
- Government and private sector should effort toward the standardization and evolutions of herbal drugs in such a way.
- Government sector effort

  Provide government funding and support, provide drug-testing laboratory, and create health regulation policy, consumer awareness programmes, and international promotion programme.

- Private sector effort

  Pharmacological screening, clinical evolutions, close determination and safety studies, development of analytical protocols for finished products

By the process of standardization, traditional drug would form a part of a primary health care in our community and the drug will come in light, which are only use as a traditional treatment in society.

D_{21} Preparation and evaluation of topical herbal formulation from *Cassia sophera Linn* leaf extracts

R. Uma Maheswari, G. Tamilarasi, AR. Mullaicharam[1], S. Angeline Premlatha*, B. Lakshmi Narayanan, G.S. Devika, K. Jeyavanitha, J. Sathish

Department of Pharmaceutics, Ultra College of Pharmacy, Madurai 625 020.

1. Department of Pharmaceutics, Nandha College of Pharmacy, Erode.

Cassia sophera Linn, is an Annual Shrub grows in the tropical regions of India. The herb is well known for its different medicinal properties in traditional system of India in medicine. Leaves of the plant exhibits the alcohol and water soluble extractives with known antimicrobial and anti-inflammatory activities.

To substantiate this claim, the present study was undertaken to evaluate the invitro antibacterial activity for both (Gram positive and Gram Negative) organisms of the formulation prepared by using emulsion ointment base and vanishing cream base. Activity was evaluated by measuring the zone of inhibition, and zone was compared with the standard drug of known antibacterial activity.

D_{22} Comparative microbiological and chemical study of Balarishta with respect to sterile condition

Sarita Pande*, B.K. Shrikhande, V.S. Meghare

Research Chemist, Baidyanth Research Foundation Ltd., 20, Great Nag Road, Nagpur 440 009

Asav and arishtas i.e. medicated spirituous liquors are popularly used in ayurvedic practices. These preparations occupy prime position on account of their superiority to the other preparations. The self generated alcohol plays an important role in making these preparations more superior. From ancient days, Dhataki flowers (*Woodfordia fruticosa* Linn) are being used as fermentation inducing agent. But we are still in dark about the actual fermenting organism or agent of Dhataki flowers. As an advancement in the technology, yeast is used for fermentation, which induces the fermentation within 24 hours and helps to complete it very quickly as compared to conventional method.

An attempt was therefore made to isolate and identify the organisms responsible for fermentation from the ingredients of the ayurvedic drug with respect to Balrishta. The study was also planned to assess the influence of sterile conditions on the production of alcohol and on biological load. Ingredients of *Balrishta* were categorized in three combinations viz. jaggery solution, jaggery solution & dhataki, and total ingredients of *Balrishta*. More alcohol production was found in Jaggery solution than the other ones in sterile condition. The microbiological study shows no much difference in biological load in both conditions but there was remarkable difference in the types of microorganisms. Ten fungal species, one yeast and three bacteria were isolated and identified from the ingredients of Balarishta. The further study is under process.

D_{23} Formulation and evaluation of a herbal product for acne vulgaris

D' Mello P.M, Shinde Smita*

Department of Pharmacognosy and Phytochemistry, K.M.Kundnani College of Pharmacy, Worli, Mumbai.

Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous follicle characterised by comedones, papules, pustules, cysts, nodules and scars in certain sites like face, neck, upper trunk and arms.Propionibacterium acnes has been implicated as a causative organism for acne vulgaris which colonises in an environment rich in sebum.The treatment modalities for acne are usually aimed at decreasing the P.acnes population,producing anti-inflammatory effect and decreasing the sebaceous gland

activity.Since inflammatory conditions are associated with free radical production,plant materials possesing antioxidant activity are also beneficial.

In the present investigation for screening plants which will be beneficial in the treatment of acne,the screening strategy has been aimed at plant materials with good antibacterial activity against P.acnes and antioxidant activity.We have screened various plants like *Berberis aristata* (Berberidaceae), *Pterocarpus santalinus* (Fabaceae) and *Bombax malabaricum* (Bombacaceae) for their antibacterial and antioxidant activity.

A herbal cream formulation was formulated using the various concentrations of the plant materials.Amongst the plant materials screened for their various activities, *B.aristata* demonstrated a strong antibacterial activity against *P.acnes* followed by *B.malabaricum* and *P.santalinus*.

The antioxidant activities of the plant extracts were evaluated by DPPH free radical scavenging method.P.santalinus (hydroalcoholic extract) exhibited highest activity (EC50=13.9 mcg/ml).The herbal cream formulated with various combinations of the extracts was evaluated for its antiseptic activity against P.acnes and antioxidant activity.

The herbal products have demonstrated significant activity when screened for antibacterial and antioxidant activity.

D_{24} Formulation and development of topical antifungal gel of lawsone

Pawan Chaware*, Navneet Garud[2], Minal Dombe, D.R.Chaple

1. S.N.Institute Of Pharmacy, Pusad (M.S.).
2. School of studies in pharmaceutical sciences, Jiwaji University, Gwalior (M.P.).

The project was undertaken with aim to design gel formulation for topical delivery of lawsone as herbal antifungal drug obtained from *Lawsonia inermis* belonging to family *Lyththraceae*. The project was done to explore the herbal traditional medicine in the context of modern science and to study the antifungal activity of lawsone in comparison with standard antifungal drugs in the topical gel formulation.

Lawsone was obtained from aqueous alkaline extraction and then digestion with alcohol from fresh leaves of Lawsonia inermis. Different formulations containing lawsone and carbopol 940 or HPMC were prepared. These formulations were evaluated on the basis of physical parameters, rheological behavior, stability and antifungal activity and the final preparation was optimized. Most commonly occurring topical pathogenic fungi were used for the antifungal evaluation of lawsone gel.

Comparative studies were done with standard antifungal agents like Griseofulvin and Cotrimazole.

The study revels the fact that Lawsone containing formulation shows significant action against topical pathogenic fungi and also formulation shows stability for considerable time.

D_{25} Aphrodisiac activity studies on *Turnera aphrodisiaca* ward

Suresh Kumar* and Anupam Sharma

University Institute of pharmaceutical sciences, Panjab University Chandigarh 160 014

Turnera aphrodisiaca Ward is reputed as an aphrodisiac throughout the world. Despite a long tradition of use as aphrodisiac, no systematic work has ever been carried out on this plant to validate its traditional use. Authors opine that non-availability of pharmacognostic standards, which help in identification of plants, is responsible for sporadic pharmacological reports on this potential plant. Pharmacognostic standards have been developed for *T. aphrodisiaca* by the authors in their previous work, which are instrumental in selecting the authentic plant. In present investigation, various extracts viz., petroleum ether (60-80°C), chloroform, methanol and water extracts, alkaloidal fraction and volatile oil of *T. aphrodisiaca* were screened for aphrodisiac activity in mice. Mounting behaviour was used as a parameter to screen aphrodisiac activity. *T. aphrodisiaca* aerial parts were extracted using solvents in increasing order of polarity viz., petroleum ether (60-80°C), chloroform, methanol and water. All the extracts were screened for aphrodisiac activity at various dose levels, i.e., 50, 100, 200 or 400 mg/kg, p.o. Chloroform extract exhibited significant activity at a dose of 200 mg/kg while methanol extract showed mild activity at 200 or 400 mg/kg. Volatile oil of *T. aphrodisiaca* was found to be devoid of aphrodisiac activity. Qualitative phytochemical screening showed the presence of alkaloids in chloroform extract. Thus, alkaloidal fraction was isolated from aerial parts of *T. aphrodisiaca*, and tested for aphrodisiac activity at dose levels of 25, 50, 75 or 100 mg/kg, p.o. Maximum activity was observed at the dose of 50 mg/kg upon acute administration. Chronic studies are in progress on alkaloidal fraction of *T. aphrodisiaca*.

D_{26} Antioxidant studies of conventional and microwave extracts containing phenolics and flavonoids

Shrishailappa Badami, Christy K Jose*, Geetha B, and Suresh B.

Department of Pharm. Chemistry, JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

Plant phenolics including flavonoids are known to possess a variety of biological properties.It is shown that microwave extraction is a good alternative for conventional extraction methods. Hence, in order to compare the similarity between the conventional and microwave extracts in terms of their antioxidant activity, total phenolics and total flavonoids, the present work was undertaken.

The yields obtained by the microwave extraction procedure were found to be either almost similar or higher than the conventional extraction. The microwave extraction of black catechu, green tea, Cinchona, Cinnanmon and pale catechu gave higher yields compared to the conventional method. The total phenolic content of all the extracts obtained by microwave methods was found to be high when compated to conventional extracts. The microwave extraction procedure also helped in improving the total flavonoid content of the extracts in case of *Caesalpinia sappan*, black catechu, clove, green tea and Curcuma. The other extracts showed almost similar flavonoid content when compared to conventional extracts. In the antioxidant studies using DPPH method and nitric oxide radical inhibition methods, the IC_{50} values obtained for the microwave extracts were found to be either low or almost similar to those obtained by conventional extracts. The microwave extracts of black catechu and clove showed low IC_{50} values in both the methods when compared to conventional extracts. The Cinchona extract also gave low IC_{50} value in nitric oxide method.

D$_{27}$ Multiple marker-based standardization of the polyherbal ayurvedic formulation–triphala Guggulu

Milind S. Bagul*, Harish Padh and M. Rajani

B.V. Patel Perd Centre, Thaltej, Ahmedabad 380054, Gujarat, India

Most of the formulations of Indian systems of medicine use plant based materials and minerals in their preparation. Due to the complex nature and inherent variability of the chemical components of the plant based drugs and the changes that occur during the manufacturing processes of the formulations, it is a challenging task to evaluate them phytochemically and to establish quality control parameters. It has been widely accepted that the classical formulations are effective due to the synergism of various chemical components present therein. Hence, multiple marker based phytochemical evaluation of these polyherbal formulations is essential to bring the quality of the formulations to international standards.

In the present study, qualitative, semi-quantitative and quantitative phytochemical analysis of the reputed ayurvedic formulation *Triphala guggulu* (containing guggulu, triphala and pippali) was carried out using chemical as well as biological markers, viz. Z-guggulsterone, piperine gallic acid and ellagic acid, by establishing detailed TLC finger printing profiles and methods for the quantification of these markers using HPTLC. Of the four markers, Z-guggulsterone, one of the active principles of guggulu, the major ingredient of the formulation, was found to be 0.13 and 0.28% in the samples analyzed. Results will be presented with finger print profiles, chromatograms and HPTLC method validation parameters.

The methods developed can be adopted for routine quality control of Triphala guggulu.

D$_{28}$ Standardization of an ayurvedic medicated oil using modern analytical parameters

A.J. Baxi*, AbhishekKumar& B.N. Sinha****

*Institute of Ayurvedic pharmaceutical sciences, Gujarat Ayurved University

**Department of Pharmaceutical Sciences, Birla Institute of Technology, MESRA, Ranchi –835215

From time immemorial many of the indigenous plants have been used as drugs in the Ayurvedic system of medicine. The attractive features of the herbal drugs are that they are easily and readily accessible, cheap and virtually free from undesirable side effects. Ayurveda, one of the oldest systems of medicine, is based on its holistic approach towards the restoration and maintenance of health of the human being. Aushadh(drugs) is one of the most important areas of Trisutra Ayurved(cause,symptom and drugs) revealed by Brahma.

Ayurvedic classics emphasize the importance of factors like proper identification, mode of collection, preservation and qualities of an ideal drug, which may influence the clinical efficacy. In the ancient times the physicians themselves used to either supervise or carry out all the steps starting from the identification to the use of prepared drug. Hence the quality of prepared drug was not a problem. But today, the physician only due to large population cannot control qualityof the drug. Quality control professionals are doing this work.

In this regard, present study is an attempt to standardize the Nirgundi taila, which has been used internally for scrofula, and when applied externally it relieves arthritis.

This work has been done in order to study the effect of moorchhan on the oil and to standardize the oil quantitatively with reference to the presence of one component, Colchicine, which is available as marker. We have also tried to set up the physicochemical standards of the oil by analyzing various samples of oils prepared in different batches.

The analysis revealed that the moorchan of the oil, carried out according to the classical method, increased the amount of the marker component in majority of the samples. The physicochemical parameters of the medicated oils have also been determined which support our studies.

D29 Folkloric antiamoebic herbal preparations: a study of ethnomedicinal treatment procedures among Assamese people

Amal kr. Boruah*, Kumaresan.R, Dr. D.Chetia.

Dept. of Pharmaceutical Sciences, Dibrugarh University, Dibrugarh, Assam 786 004.

The disease amoebiasis, caused by the enteric protozoan *Entamoeba histolytica*, represents a major public health problem in Assam. Many remedies have been in use in the treatment of amoebiasis, which include some plant-derived drugs also. A variety of alkaloids, degraded triterpenes, polyphenols etc. are either in use or reported to possess potent activity against the causative organisms and are well distributed among higher plants.

The local people for the treatment of amoebiasis and related complications effectively use preparations made out of indigenous plants of Assam. A survey on the available literature and among local people of Assam reveals the effectiveness of such herbal preparations against the causative organism of the disease. This report contains the method of preparation and use of some of the effective local medicines prepared and used by the people of Assam. The biological evaluation of such preparations in scientific way and systematic phytochemical study on the active constituent of the component plants may be a thrush area of research to bring the traditional treatment system into the modern form of medicine for the treatment of amoebiasis.

D30 Comparative evaluation of some ayurvedic preparations for their analgesic and anti-inflammatory properties

Patel A.S.*, Gupta P., Zambad S.P., Ghaisas M.M., Deshpande A.D.

Padm. Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune 411 018.

There are number of ayurvedic analgesic anti-inflammatory drugs available in market, some of them with single content while others with multi-component. Some preparation contains pure extract while others with crude drugs. Most of these formulations are based on their traditional ayurvedic claim. The various components of these formulations having varying pharmacological action may contribute for the difference in their therapeutic efficacy.

Hence, present study was carried out for comparative evaluation of analgesic & anti-inflammatory activity among the various single and multi-component marketed ayurvedic preparations.

Four marketed preparations (Punarnava guggul, Sinhanad guggul, Orthocure and Shallaki) were used for this study. The preparations were selected so as to compare the activities of single component, multi-component and pure extract. All above formulations were screened for their analgesic and anti-inflammatory activities. The analgesic activity was screened using tail immersion test (Thermal stimuli) and Acetic acid induced writhing method (Chemical stimuli). The anti-inflammatory activity was assessed by carrageenan induced mice paw edema method.

The results indicated that all these formulations have shown analgesic and anti-inflammatory activity. Though the multi-component ayurvedic formulations of crude ingredients have better analgesic and anti-inflammatory activity than single crude ingredient containing formulation, the formulation having the pure extract has shown best activity. Thus, the study recommends the use of pure extracts instead of using the crude drugs for better analgesic and anti-inflammatory activity.

D31 In-vitro human sperm immobilization through henna and fenugreek

Dheeraj Ahirwar*, Bharti Ahirwar and M.D. Kharya

Dept. of Pharmasciences, Dr. H S Gour University, Sagar (M.P.)

For controlling the population explosion traditional herbal drugs may play important role owing to their potential in certain aspects of fertility regulation. Fenugreek and Henna are valuable drugs of our traditional system of medication. The alcoholic extract of Fenugreek and henna seeds respectively were evaluated for their spermicidal activity. In vitro studies reveal that complete loss of human sperm mobility by alcoholic extract of henna and fenugreek seeds.

Seeds of Fenugreek (local market) and Henna (University Campus of Sagar) (M.P.) were dried, powder and Soxhleted with 95% alcohol. After recovery of alcohol, extract was used for experiment and different dilutions (1,2.3,4,5,6,10,15%) were prepared in buffer saline (pH 7.4). Fresh semen collected from healthy males was flushed in 1ml of previously warmed buffer saline at 37°C to make suspension of *spermatozoa*. Minimum 82% initial normal sperm motility and 2.6x107/cc sperm count was considered for the selection of semen samples.

Results were analyzed using student t test p value (<0.05) was considered to be statistically significant. Initial mobility of control normal sperms was 82.3%, which remained almost static (80.5%) upto 10 minutes. Sperm motility decreased with increasing concentration of alcoholic extract of Henna and Fenugreek seeds, which practically nil at 10%

concentration of alcoholic extract of Henna and 15% concentration of alcoholic extract of Fenugreek seeds.

Though effective use of the chemical contraceptives by women are not free from undesired effect and toxic manifestations. Since last decade, efforts are being made to search spermicidal agents from herbal source. The findings of our present study clearly indicate that alcoholic extract of Henna and Fenugreek seed decreased sperm motility with increasing concentration. This sperm immobilization of alcoholic extract of Henna and Fenugreek can be correlated with the finding of sperm motility by neem extract.

The findings of present study clearly indicate that alcoholic extract of Henna and Fenugreek possesses antimotility effect or spermicidal effect on spermatozoa in human semen.

D32 Antihyperlipidemic activity of combined extracts of *Camellia sinensis, Emblica officinalis* and *Apium graveolens*

N. Mahadevan, R. Meenakshi*, M.J. Nanjan, E.P. Kumar and B. Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund-643001, The Nilgiris, Tamilnadu

Hyperlipidemia is a major cause for ischaemic heart disease, an irregular thickening of the inner layer of the walls of arteries, accounts for 66% of all cardiovascular deaths. In hyperlipidemia, serum LDL cholesterol level should be reduced and HDL cholesterol level should be improved to reduce the risk of heart disease. *Camellia sinensis, Emblica officinalis* and *Apium graveolens* were reported to have antihyperlipidemic activity. However, the effect of the combined extracts has not yet been screened. Antihyperlipidemic activity of the combined extracts of *Camellia sinensis, Emblica officinalis* and *Apium graveolens* was evaluated on triton induced hyperlipidemia in rats. Aqueous extracts of leaves of *Camellia sinensis,* fruits of *Emblica officinalis* and seeds of *Apium graveolens* were prepared and subjected for antihyperlipidemic screening. These extracts were combined in a suitable ratio (1:1:2) and administered to rats by oral route at a dose of 140mg/ kg body weight. Rats were grouped in to four groups comprising of six in each group. Group I was injected with triton (0.1ml/ 100gm body weight) and group II served as a normal control. Group III served as standard control, administered with atorvastatin. Group IV was administered with the combined extracts for 6 days and triton was injected. Blood was collected by intra orbital puncture, after 6th hour, 24th hour and 48th hours of triton injection in tubes containing anticoagulant solution. Blood was centrifuged at 2000 rpm and plasma was used for the estimation of cholesterol, triglycerides and phospholipids. The combined extract showed a significant reduction in cholesterol and triglycerides levels at 6th and 24th hours. However, there was no much change in the phospholipid levels. At 24th hour, higher reduction in cholesterol and triglycerides levels were observed in combined extract treated and atorvastatin treated group, but it was found to be no much change on phospholipid levels. The combined extract showed nearly equal activity to atorvastatin.

D33 A study on traditional treatment of helminthiasis with indigenous plants in assam

Kumaresan.R*, D.Chetia, Amal KR. Boruah, Madhu sudhan Das

Dept. of pharmaceutical sciences, Dibrugarh University, Dibrugarh, Assam-786 004.

Northeast region of India is rich in varied flora and fauna. Assam is a pivot of the northeastern region, covered by temperate evergreen forest with a homeland of various ethnic groups. Many polyherbal preparations have been in use effectively among the local population for treatment of various helminthiasis ailments. A study made on the use of indigenous plants by local people for various helminthes problems reveals that the herbal preparations are used against the treatment of the ailments caused by some of the worms under the class cestoidea and nematoda. Traditional treatment has not been recorded in the study against the infestations of trematoda because of non-availability of information showing the lack of treatment against the infestation of these parasites in the traditional treatment system of Assam. The present communication is a record of 49 plants spread into 19 families having folkloric use as anthelmintics. Reports of phytochemical investigation on some of the plants are available while on some other plants such systematic study has not been reported. An exhaustive and systematic phytochemical study along with biological evaluation is required to explore the area of folklore anthelmintic treatment with indigenous plants of Assam.

D34 Antinociceptive activity of alcoholic extract of *Hemidesmus indicus* R.Br.

V.R. Rabra*, V.A.Chatpalliwar, P.R. Verma, A.J. Asnani, V.T. Kharkar

J.L. Chaturvedi College of Pharmacy, 846, New Nandanvan, Nagpur 440 009 INDIA

To study the antinociceptive activity of alcoholic extract of Hemidesmus indicus R.Br. using chemical induced pain models in mice.

Dried and powdered roots of Hemidesmus indicus R.Br. were extracted with ethanol (yield 9.2%). The suspension of solvent-dried extract (HI) was evaluated for antinociceptive activity employing the following experimental models of pain in mice: 1) Formalin-induced licking 2) Acetic acid-induced writhing. HI was administered in the dose range of 25, 50, and 100-mg/kg orally 1 h prior to the pain induction. The results are expressed as the percent inhibition of pain responses (number of paw licking in the duration of formalin test, and number of abdominal constrictions in the duration of the writhing test). Aspirin (25mg/kg) was used as the reference drug.

Results indicated that the extract exhibited significant antinociceptive activity against both the models of pain, and it blocked both neurogenic and inflammatory pain. The activity was dose-dependent that reached optimum at 50 mg/kg, which was comparable to the reference drug.

Results suggest the significant antinociceptive activity of alcoholic extract of *Hemidesmus indicus* R.Br. This activity may be related with the central mechanism or due to peripheral anti-inflammatory mechanisms, which enhance the tissue defense. The activity can be related with the significant phytochemicals like triterpenes, and beta sitosterol, reported in the root extract.

D35 Microwave assisted rapid isolation of mucilages and pectins with improved yield

Shrishailappa Badami, Om Prakash*, Geetha B, Santhosh Kumar H. Dongre and Suresh B

JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

Mucilages and pectins are polysaccharide complexes which are the most commonly available plant constituents with a wide range of applications in pharmaceutical cosmetic, food and nonfood industries. Fast and high yield methods for the isolation of mucilages and pectins help the industries in terms of their costs and fluctuations in their supply. In the present investigation, we reports a rapid microwave assisted isolation methods for several mucilages and pectins.

The yields of the mucilages obtained by microwave heating were found to be high when compared to the conventional yields. The increase in the yield by this method in case of *Moringa oleifera* and *Passiflora edulis* was found to be 211.34 and 161.51% more than the conventional product. Similarly, *Asparagus racemosus, Colocasia esculenta* and *Brassica juncea* also showed 84.68, 76.13 and 71.01% increase in the yields. In other plant sources, the increase in the yield was found to be in the range of 25.19 – 52.52%.

The yields of the pectins isolated from microwave method were also found to be more when compared to the conventional method. The yield was found to be the highest in case of *Psidium guajara* and *Persea Americana* with 191-11 and 121.27% increase, respectively. *Passiflora edulis, Cyphomandara betaceae, Citrus sinensis and Citrus reticulata* also showed increase in the yield by this method ranging between 52.31 – 69.75%. The increase in the yield of Mangifera indica pectin was the lowest.

In conclusion, isolation of mucilages and pectins under microwave irradiation using the above conditions provided better yields in lesser durations. These procedures can be used routinely in laboratories. Following these procedures in the industries, the present day fluctuations in the availability and arising costs can be avoided.

D36 Antiulcerogenic activity of alcoholic extract of *Martynia diandra* glox. in rats

P.R. Verma*, V.A. Chatpalliwar, V.R. Rabra, A.J. Asnani, V.T. Kharkar

J.L. Chaturvedi College of Pharmacy, 846, New Nandanvan, Nagpur 440 009. India

To study the antiulcerogenic activity of ethanolic extract of *Martynia diandra* Glox employing different models of gastric ulceration in rats.

Shade dried whole plant of *Martynia diandra* Glox was macerated with ethanol (yield 7.2%). The solvent-dried extract was evaluated for antiulcer activity employing the following experimental models of gastric ulcers in rats (Albino Wistar): 1) Indomethacin induced ulcers 2) Ethanol-induced ulcers, 3) Pyloric-ligation induced ulcers. The extract of *Martynia diandra* Glox (MD) was administered in the dose range of 25, 50, ad 100-mg/kg orally 30 min prior to the ulcer induction. The ulcerative indices were measured using the scoring method that ranged with loss of normal morphology to perforations. In addition, gastric total acid activity and volume was measured in pyloric-ligated rats. Cimetidine (100 mg/kg) was used as the reference drug.

The alcoholic extract of *Martynia diandra* Glox decreased the ulcerative lesions induced by indomethacin, ethanol and pyloric ligation in rats. The dose of 50 mg/kg was found to be the optimum amongst the doses tested. When tested in pyloric-ligated model, MD reduced the gastric volume, but did not modify pH of the gastric content.

Results suggest the significant antiulcerogenic activity of alcoholic extract of *Martynia diandra* Glox. This activity may not be related with the antisecretory mechanism, as indicated in pyloricligated model. Hence, the antiulcerogenic activity seems to be due to cytoprotective mechanisms, which enhance the mucosal defense, without interfering with the gastric acid secretion.

E_1 Beneficial effects of *Zingiber officinale* on experimentally induced hyperlipidemia and its correlation with 5-HT actions

Kadnur V Sanjay* and Ramesh K Goyal

Research Scholar, L.M. College of Pharmacy, Navrangpura, Ahmedabad 380 009

To standardize and evaluate the beneficial effects of methanolic extract and its fractions from dried rhizomes of *Z. officinale* on fructose induced hyperlipidemia, hyperglycemia and hyperinsulinaemia and to correlate with 5-HT actions of *Z.officinale*.

Wistar rats of either sex were divided into five groups, Group I (control), Group II (hyperlipidemic rats, 20% fructose given in drinking water), Group III (hyperlipidemic rats, treated with methanolic extract of *Z. officinale* 250 mg/kg), Group IV (hyperlipidemic rats, treated with petroleum ether fraction of methanolic extract of *Z. officinale* 100 mg/kg), Group V (hyperlipidemic rats, treated with toluene fraction of methanolic extract of *Z. officinale* 100 mg/kg), The drugs were administered orally for 3 weeks, at the end of which blood samples were analyzed for serum glucose, insulin, cholesterol, triglycerides, HDL-cholesterol, LDL, and VLDL. All the extracts and fractions of *Z.officinale* were standardized for 5-HT modulating compound 6-gingerol content.

There was a significant increase in fasting serum levels of glucose, insulin and lipid profile and body wt gain in hyperlipidemic control rats as compared to normal control rats. There was a significant reduction in fasting serum glucose levels, lipid profile levels and body wt, and no changes in serum insulin levels in methanolic extract and petroleum ether fraction of methanolic extract of *Z.officinale* treated rats as compared to hyperlipidemic control rats. Toluene fraction of methanolic extract produced only decrease in fasting serum lipid levels, it failed to produce decrease in glucose as well as insulin levels. Methanolic extract and petroleum ether fraction of methanolic extract was found to contain higher concentrations of 6-gingerol, a 5-HT modulating compound .Whereas the toluene fraction contained very low concentration of 6-gingerol.

Since toluene fraction of methanolic extract did not produce anti-hyperglycemic effect and had lower concentrations of 6-gingerol a 5-HT modulating compound, it can be hypothesized that effect of *Z.officinale* on glucose and lipid profile may be mediated through 5-HT receptors.

E_2 Self-association and interactions of gabapentin with artificial biomembrane: physicochemical and biological implications

A N Nagappa*, Kole P.L., Pandi V., Srivatsava R.C, Vivek D*, Srinivas D*, D'Souza U.P*.

Pharmacy Groups, BITS, Pilani 333031, Rajasthan

* Department of Pharmacology, SCS College of Pharmacy, Harapanahalli, Karnataka 583131

Many pharmacologically active compounds are amphiphillic or hydrophobic molecule, which may undergo different kinds of association, and whose site of action in the organism frequently is the plasma membrane. Investigations carried out by Srivastava et al., on the wide variety of drugs have substantiated that the liquid membranes generated by the surface active drugs at the site of their action, acting as the barrier to the transport of relevant permeants might be an important step common to the mechanism of action of all surface active drugs. These investigations have led to phenomenon called as "liquid membrane hypothesis of drug action". The structure of Gabapentin (GBP), which includes both hydrophilic and lipophilic part in its structure and thus thought to have the surface-active property. Like, other surface active drugs, the ability of GBP to form the liquid membrane in series with the supporting membrane at the interface is established and its effect on the permeation of the relevant amines and essential ions is found relevant to the mechanism of action of GBP.

E_3 Peripheral action of reserpine analogs – evaluation by pharmacological & biochemical methods

S. Satyanarayana*, N. Srinivas, K. Sushruta and B. Krishna Murthy

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam – 530 003.

Reserpine, an alkaloid isolated from Rauwolfia serpentina was introduced for hypertension and schizophrenia in 1950's and was replaced by other drugs by the end of 1970's due to its unwanted central sedation and parkinsonism precipitation on chronic use. Attempts were made earlier to modify the structure of reserpine to reduce its central action but were not successful. In the present study two quarternary analogs namely reserpine methiodide (RPMI) and reserpine methonitrate (RPMN) were synthesized and evaluated for their biological activity compared to reserpine (RP).

Both RP and analogs were tested for LD_{50} by two different routes in mice and rats . Their influence on blind screening, central effects like barbiturate hypnosis, spontaneous motor activity, body temperature, motor incordination, pinna and corneal reflexes , plapebral test , swimming performance was evaluated in mice. Their influence on CAR, pupil size and blink response was evaluated in rats and rabbits respectively. Their influence on the depletion of noradrenaline (NA, exists centrally and peripherally), serotonin (5-HT, mostly exists peripherally) and Dopamine (DA, exists mostly centrally) was evaluated in rats by estimating their urinary metabolites before and after treatment with reserpine/analogs.

The LD_{50} of RPMI and RPMN was much higher than RP in mice and rats indicating their low level of toxicity (RP 178 mg/kg, P.O. and 4.43 mg/kg IP in mice; 355mg/kg, P.O. and 50 mg/kg IP in rats; analogs LD_{50}>500mg/kg P.O./IP in mice/rats). Reserpine reduced central effects in blind screening, prolonged barbiturate sleeping time, reduced spontaneous motor activity, body temperature, swimming time, CAR and prolonged miosis. The analogs did not produce the above effects even at equivalent or twice the dose of RP indicating their non entry into CNS. Moreover reserpine increased the urinary levels of VMA, 5-HIAA and HVA (metabolites of NA, 5-HT and DA respectively) while analogs increased VMA and 5-HIAA only without much change in HVA and confirm the peripheral disposition of the analogs. The cardiovascular activity due to peripheral action was seen with reserpine as well as with analogs. The study confirmed the peripheral action of the analogs.

E_4 Effect of acetyl-11-Keto-β-boswellic acid (AKBA) on indomethacin inducted gastric damage in rats

Mahendra Bishnoi*, C.S. Patil, A. Kumar S.K. Kulkarni

Pharmacology Division, University Institute of Pharm. Sciences, Punjab University, Chandigarh 160 014

Non-steroidal anti-inflammatory drugs (NSAIDs) are the most commonly used remedy for the treatment of inflammatory diseases and are associated with major side effect of gastric ulceration. Attempts have been made to develop NSAIDs devoid of these gastric shortcomings. The present investigation was designed to study the effect of acetyl-11-keto-β-boswellic acid (AKBA), a noncompetitive inhibitor of 5-lipooxygenase enzyme, on indomethacin-inducted gastrointestinal ulceration in rats. Animals were chronically (7days) treated with indomethacin (5 mg/kg p.o.) and there after were observed for ulcer index, gastric acidity (pH, total and free acidity), lipid peroxidation and myeloperoxidase activity, and mortality rate. Chronic administration of indomethacin (5 mg/kg p.o.) resulted in mortality, gastric damage associated with increased ulcer score, total and free acidity, decreased pH, increased myeloperoxidase an lipid peroxidation, respectively. Treatment with AKB (100 mg/kg p.o.) significantly exhibited lesser gastric damage in comparison to indomethacin treated animals. These results indicate that lipoxygenase inhibition may play a vital role in the prevention of NSAID-induced gastric inflammation and ulceration. Based on this, our results suggest a need for the development of dual (COX/LOX) acting inflammatory drugs, which could not only devoid of gastrointestinal side effects but also decrease the therapeutic dose of NSAIDs.

E_5 *In-vitro* cytotoxicity study and apoptosis inducing property of the standardized fruit extract of *Terminalia pallida* against human cancer cell lines.

L. Manikandan[1]*, G.P. Senthilkumar[1], S. Bhattacharya[1], Sutapa, Chakraborty[2], Madhumita Roy[2], U.K. Mazumder[1] and M. Gupta[1]

1. Department of Pharmaceutical Technology, Jadavpur University, Kolkata
2. Chittaranjan National Cancer Institute, Kolkata.

Standardized fruit extract of *Terminalia pallida* was evaluated for their cytotoxicity against four human cancer cell lines - acute myeloblastic leukemia (HL60), chronic myelogenic leukemia (K562) cervical epithelial carcinoma (HeLa) and breast adenocarcinoma (MCF-7. Cytotoxicity was assayed by trypan blue dye exclusion assay and 3-(4,5-dimethyl thiazole-2yl)-2,5-diphenyl tetrazolium bromide (MTT) reduction assay. [^{3}H] thymidine uptake assay was also carried out to study the effect of the extracts on cell proliferation.

Standardized fruit extract of *Terminalia pallida* exhibited strong cytotoxicity against the tested cell lines in a dose dependent manner at the tested concentrations. Further investigation on cellular morphological changes by fluorescent microscopy, DNA fragmentation study by agarose gel electrophoresis and flow cytometric analysis indicated that the cells treated with the standardized extract underwent apoptotic cell death. Thus from the present investigation it can be concluded that the standardized fruit extract of *Terminalia pallida* acts by the induction of apoptosis in human cancer cell lines

E_6 Novel monomeric ruthenium (II) chelates exhibited cytotoxicity against human leukemic cell lines

Hira Choudhury[1]*, S. Bhattacharya[1], R.Suresh[1], L.Manikandan[1]. Sutapa Chakraborty[2], Madhumita Roy[2], U.K.Mazumder[1] and M.Gupta[1]

1. Department of Pharmaceutical Technology, Jadavpur University, Kolkata

2. Chittaranjan National Cancer Institute, Kolkata.

Bis (1,10-phenanthroline) ruthenium (II) complexes containing adenosine, picolinic acid and acetazolamide as ligands have been prepared and fully characterized by elemental analysis, IR, H^1 NMR and FAB Mass spectroscopy. The cytotoxicity of this series of bis (1,10-phenanthroline) ruthenium (II) complexes was tested against two human cancer cell lines - acute myeloblastic leukemia (HL60) and Chronic myelogenic leukemia (K-562). Cytotoxicity was assayed by trypan blue dye exclusion assay and MTT assay. [^{3}H] thymidine uptake assay was also carried out to study the effect of the chelates on cell proliferation.

The compounds displayed promising cytotoxicity against the tested cancer cell lines in a dose dependent manner. Thus from the present investigation it can be concluded these monomeric ruthenium (II) chelates exhibited significant cytotoxicity against the tested human leukemic cell lines.

E_7 *In-vitro* DNA binding and *in-vivo* anticancer activity of ruthenium (II) complexes

S. Bhattacharya[1*], R.Suresh[1*], Hira choudhury[1], L. Manikandan[1] Sutapa Chakraborty[2], Madhumita Roy[2], U.K. Mazumder[1] and M.Gupta[1]

1. Department of Pharmaceutical Technology, Jadavpur University, Kolkata
2. Chittaranjan National Cancer Institute, Kolkata.

Ruthenium (II) complexes containing acetazolamide, 2-pyridyl benzimidazole and 5-substituted-8-hydroxy quinoline derivatives as ligands have been prepared and fully characterized by elemental analysis, IR, H^1 NMR and FAB Mass spectroscopy. These ruthenium (II) complexes were studied for their *in vitro* DNA binding property and *in vivo* anticancer property against transplantable murine tumor.(EAC). Experimental parameters such as increase in life span, tumor volume and hematological parameters were observed. *In vitro* binding of the complexes with calf thymus DNA was also studied by absorption spectroscopy.

From the present investigation it can be concluded that these ruthenium increased the life span of the tumor bearing mice and reduced the tumor volume. These chelates also restored the altered hematological parameters. *In vitro* calf thymus DNA intercalating studies showed a positive interaction between the drug and DNA. Thus it may be concluded the complexes may interfere with the functioning of electron rich molecules such as DNA in the cell and exert its antitumor activity.

E_8 Amelioration of cardioprotective activity by *Tinospora cordifolia* in myocardial ischemia and reperfusion injury

Rajeswara Rao P., Veeravalli KK, Routhu KV*

Department of Pharmaceutical Sciences, Andhra Unviersity, Visakhapatnam 530 003

Oxidative stress plays a major role in the biochemical and pathological changes associated with myocardial ischemic reperfusion injury. It has been suggested that the beneficial effects of reperfusing the ischemic myocardium might be in part reversed by the occurrence of reperfusion injury. The need to identify agents with a potential for preventing such reperfused ischemic damage has assumed great importance. One possible mechanism could be the generation of oxygen derived free radicals. The present study was designed to investigate the effects of pretreatment with alcoholic extract of *Tinospora cordifolia* in an *in vivo* rat model, myocardial infarction was produced by occlusion of the left descending coronary artery for 30 min followed by 4 h of reperfusion. Infarct size was measured by using the staining agent TTC (2,3,5-triphenyl tetrazolium chloride). Lipid peroxide levels in serum and in heart tissue were estimated spectrophotometrically by known methods. A dose dependent reduction in infarct size and in lipid peroxide levels of serum and heart tissue were observed with the prior treatment of *T.cordifolia* with various doses for seven days compared to control animals. Hence, the study suggests the cardioprotective activity of *T. cordifolia* in limiting ischemia-reperfusion induced myocardial infarction.

E_9 Hypotensive and β– adrenoreceptor antagonistic activity of DPJ 955 in rats.

Nandakumar K.[1*], Singh R.[1], Bansal S.K.[1], Bodhankar S.L.[1], Mohan S. Coumare[2], and Jindal D.P.[2]

1. Department of Pharmacology, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune – 411 038.
2. University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh-160 014.

To study hypotensive and b adrenoreceptor antagonistic activity of DPJ 955 in rats.

Pharmacological evaluation was carried out using rat blood pressure as described by Kannan et al., (1996) with modifications and invitro b_2 adrenoreceptor antagonistic activity was assessed using isolated rat uterus as described by Levy and Tozzi (1963).

DPJ 955 (1, 3, and 10 mg/kg, i.v.), propranolol (500 mg/kg, 1and 2mg/kg i.v) and atenolol (17.5, 50 and 175 mg/kg, i.v) alone produced significant reduction in blood pressure and heart rate in a dose dependent manner. Isoprenaline alone (300 ng/kg, 1 and 3mg/kg, i.v.) produced significant increase in heart rate (tachycardia) due to b_1 adrenoreceptor and reduction in blood pressure (b_2-receptor). DPJ 955 (2 mg/kg, i.v.), propranolol (1 and 2 mg/kg, i.v.) and atenolol (175 mg/kg) blocked isoprenaline induced tachycardia and hypotensive effect. Cumulative administration of isoprenaline ($1.2x10^{-4}$, $1.2x10^{-3}$ and $1.2x10^{-2}$ mM) abolished spontaneous contraction of uterus dose dependently. Propranolol ($1x10^{-2}$ mM), DPJ 955 (10 mM) and atenolol (30 mM) blocked isoprenaline induced relaxation of rat uterus. The degree of selective b_1 adrenoreceptor antagonistic activity was in the order of atenolol > DPJ 955 > propranolol.

It is thus concluded that DPJ 955 possessed non-selective b- adrenergic blocking activity and selectivity to b_1 adrenoreceptor is less than atenolol but greater than propranolol.

E_{10} Effect of finasteride on sensitization to ethanol- induced locomotor stimulation

P. Bhutada*, K. Hirani, N S Jain, R R Ugale, C. T. Chopde

Pharmacology Division, University Department of Pharm. Sciences, Nagpur University Campus, Nagpur 440 033

Contemporary theories of drug abuse suggest that behavioral sensitization plays an important role in addiction. However few studies have examined the mechanisms underlying behavioral sensitization to ethanol. Allopregnanolone, a neuroactive steroid that positively modulates $GABA_A$ receptor is reported to mediate some of the behavioral effects of ethanol including reward, euphoria and discriminative stimulus effects. Finasteride is a competitive blocker of the enzyme 5a-reductase responsible for metabolizing progesterone to allopregnanolone. The present study was aimed to ascertain whether the inhibition of neurosteroid biosynthesis by finasteride (25 mg/kg, s.c.) pretreatment prevents the development of sensitization to the locomotor stimulant effect of ethanol (2 g/kg) in DBA/2J male mice. Mice received daily injection of ethanol or saline for 10 days. Locomotor activity was monitored immediately for 20 min on day 1, 4, 7 and 10. Day 11 to 14 were non-treatment days and animals were challenged on day 14 with ethanol before measuring the locomotor activity. Finasteride or vehicle was administered twice a day at 12 hr interval to ethanol or saline treated group. Administration of ethanol on each of the five trial resulted in behavioral sensitization in control groups. Administration of finasteride prior to ethanol on each trial blocked development of sensitization on the challenge day. Finasteride per se did not alter locomotor activity in mice. Assessment of blood ethanol levels 20 min after administration indicated that finasteride did not change the pharmacokinetic of ethanol. These results indicate an important role for allopregnanolone in development of sensitization to locomotor stimulant effect of ethanol. [Supported by emeritus grant of AICTE, New Delhi (CTC) and senior research fellowship of CSIR, New Delhi (KH).

E_{11} Antidepressant –like effect of adenosine receptor antagonists in Porsolt's forced swim test: Modulation by serotonergic agents#

Kalaiyarasi C*, Nishant S Jain, Khemraj Hirani Rajesh Ugale, C T Chopde[CA]

Department of Pharmaceutical Sciences, Nagpur University Campus, Nagpur - 440 010 (MS)

Funded by emeritus grant AICTE, New Delhi and Senior research fellowship, CSIR, New Delhi

Adenosine is a potent modulator that has a pervasive and generally inhibitory effect on neuronal activity in the CNS and is known to act via four distinct receptor subtypes, A_1, A_{2A}, A_{2B} and A_3. Recently, adenosine antagonists have also been shown to posses antidepressant like activity in the animal model of depression i.e force swim test (FST). A growing body of evidences suggests that adenosine and 5-HT might interact in CNS to exert their effects with the fact that adenosine and its analogs regulate 5HT release. The present study investigated the effect serotonergic agents on adenosine analogs induced effect on immobility time in force swim test in mice. Methods: First, the effects induced by the selective A_1 and A_{2A} receptor agonist i.e. CPA and CGS 21680, respectively or selective antagonists i.e. DPCPX and CSC or non-selective antagonist, caffeine on the immobility time of mice in force swim test were assessed. Secondly, the modulatory effects of serotonergic agents like serotonin releaser, fenfluramine or SSRI, fluoxetine and selective 5-HT_{1A} agonist, 8-OH-DPAT or 5-$HT_{1B/1C}$ agonist, TFMPP or 5-$HT_{1A/1C}$ agonist, DOI or 5-HT neuronal store depalter, P-CPA on adenosine analogs induced changes in immobility time in FST were observed. Mice were subjected to FST for 6 min after acute administration of test drugs. Result: Selective A_1 and A_{2A} receptor agonist i.e. CPA and CGS 21680, respectively, on acute administration (0.01-0.1 mg/kg, IP) dose dependently shown to produce sever behavioral depression as evident from increase in immobility time as compared to control, while selective antagonist, DPCPX (0.1-10 mg/kg, IP) and CSC (0.1 or 10 mg/kg,

IP) or non-selective antagonist, caffeine (0.5-3 mg/kg, IP) shown to produced antidepressant-like effect in FST in the doses which are devoid of any motor effects. Pretreatment with serotonergic agents like fenfluramine (10 mg/kg, IP), fluoxetine (5 mg/kg, IP), 8-OH-DPAT (0.1 mg/kg, SC), TFMPP (4 mg/kg, SC) or DOI (2 mg/kg, SC) reversed the CPA or CGS 21680 induced depression in FST. Moreover, these agents also potantiated the antidepressant effect of selective antagonist, DPCPX (5 mg/kg, IP), CSC (5 mg/kg, IP) or non-selective antagonist, caffeine (0.5 mg/kg, IP). At these doses the serotonergic agents per se did not modify the duration of immobility. Pretreatment with P-CPA (300 ' 3 mg/kg, IP), a depleter of 5-HT neuronal store, block the influence of fenfluramine and fluoxetine on antidepressant-like effect of selective adenosine A_1 and A_{2A} receptor antagonists. Conclusion: Thus the mechanism underlying the antidepressant-like effect of A_1 and A_2 receptor antagonists might be partially related to increase in serotonergic transmission besides A_1 and A_2 receptor antagonism. Hence the development of new adenosinergic agents that modulate the endogenous serotonin levels might be novel approach to treat behavioral depression.

E_{12} Effect of serotonergic antidepressants on cognitive functions in isolation and chronic mild stress induced depression in rats

Patel R.K.*, Ashok Kumar SN, Suresh B & Ramanathan M

Department of Pharmacology, JSS College of Pharmacy, Ootacamund, TN 643001

Serotonergic selective antidepressants drugs are reported to claim no anticholinergic effect and there by minimum effect on memory. In the present study selective serotonergic reuptake inhibitor and enhancer were evaluated for their cognitive behavior in both depressive and non depressive animals. Depression was induced by 60 days isolation in litter and by applying chronic unpredictable mild stress for 21 days. Depression was conformed by behavioral despair test. Acquisition of radial arm maze test was used to evaluate the cognitive function. Results indicate that depression was induced in both the models and memory deficit was observed with depressive rats. Treatment of Fluoxetine, Sertraline, Tianeptine attenuated the cognitive deficit observed in depressive rats. In non-depressive rats all these drug produced retention deficit which was found to be parameter and model dependent. It can be concluded that SSRI and SSRE can improve the cognitive deficit in depression and TIANEPTINE produce better effect in stress induced depression model.

E_{13} To study the Effectiveness of Some Antihypertensives used in Cyclosporin 'A' Induced Hypentension

Prem Kumar N[a*], Inamdar. M.N [b], Venkataraman B.V[c]

*a. Department of Pharmacology, Krupanidhi College of Pharmacy, Bangalore.

b. Department of Pharmacology, Al – Ameen college of Pharmacy, Bangalore.

c. Department of Pharmacology, St.John's Medical College, Bangalore.

Cyclosporin 'A'(CSA) is used as major immunosuppressive agent after organ transplantation, but CSA induces hypertension. Calcium channel blockers (CCB) have achieved the status of 'preferred' drugs to treat this hypertension. CSA treatment is associated with hypertension by blockade of endothelium dependent relaxation. Management of hypertension will be effective only by avoiding interaction between antihypertensive regimens & CSA. Hence, experiments were designed to evaluate significant drug-drug interaction by CSA & different antihypertensive agents. One set of rat (n = 6) were treated only with CSA (20 mg/kg/day) and four set of rats (n = 6) were treated with CSA & different antihypertensive such as diltiazem, enalapril, propranolol, losartan.

Isolated thoracic aortic rings (4.– 5 mm) were suspended in organ chamber containing kreb's Henseleit solution (37o C, 95% O_2, 5% CO_2). The maximum endothelial dependent relaxation to cumulative doses of acetylcholine was significantly decreased in CSA, CSA plus diltiazem & CSA plus propranolol treated rats. However, endothelium dependent relaxation increased in CSA along with losartan treated group of rats. This experiment suggests that, concomitant usage of diltiazem with CSA & propranolol with CSA elevated plasma level of CSA. The increase in CSA plasma level augmented the vascular tone by decreasing the release of EDRF & hence increased vascular smooth muscle sensitivity to circulating catecholamine. These findings in animal studies indicate that diltiazem is not the safer drug as reported earlier in the treatment of CSA induced hypertension. Further studies have to be explored in human volunteers.

E14 Development of simulation software on computers for pharmacology practical classes of B.Pharm. course to minimize the use of animals

Jignesh L. Patel*, Natvar J. Patel, Praful D. Bharadia, Narendra J. Patel°, Hitendra R. Patel°, Yashesh Lele°, Dhavan Jani°

Shree S. K. Patel College of Pharm. Edu. and Research, A.M. Patel Institute of Computer Studies, Ganpat Vidyanagar, Kherva-382711, Mehsana, Gujarat.

In four year Bachelor of Pharmacy programme, animal tissues are used by the students for experiments in Pharmacology. Each year more than 5,00,000 animals are sacrificed at pharmacy colleges only for educational purpose. As per prevention of Cruelty to Animal Act, 1960, the use of animals in experiments should be minimized and they are used only when there is no alternative available. The use of alternatives is mandatory by law as stated in Rule 17(d) of the Act and any use of animals in this context is now illegal. The Act permits the use of animals for limited number of practicals only. So there is an extreme need of alternatives that can be useful to minimize the use of animals and also able to met the existing teaching objectives.

Computer Software can effectively replace the animal use and also complement the existing system. We have developed one interactive simulation software 'Virtual Kymograph Simulator' for frog's heart experiments as per present pharmacy syllabus, which simulates the scientifically perfect effects of necessary drugs used for perfused frog's heart experiments. e.g. dose dependent effect of agonist and antagonist, distinguishing the stoppage of heart in systole and diastole, increase in contraction when heart start after stoppage because of increased in end diastolic volume (Sterling law), death of animal if high dose is given etc.; and with many features like zooming effect up to 300%, automatic labeling of dose, drug and conc., student details etc. The software also facilitates identification of unknown drug with password protection, which will be very much useful to carryout practice exams. The software will be useful to all pharmacy students and teachers and it will be highly effective when the software will be used in combination with real tissue experiments.

E15 Comparative behavioural and biochemical evaluation of *Ginkgo biloba* and nifedipine in global ischaemic rats

Harisudhan T*, Kumaran D, Suresh B & Ramanathan M.

Department of Pharmacology, J.S.S College of Pharmacy, Ootacamund, TN-643 001.

The present study was designed to compare the effect of calcium channel blocker (vasodilator) and *Ginkgo biloba* (Vasodilator + Anti-oxidant) in global ischaemia. The drugs nifedipine (10mg/Kg) and *Ginkgo biloba* (100 mg/Kg) were administered for 7 days before inducing ischaemia. Four-vessel occlusion method was used to induce global ischaemia. Parameters used for comparative evaluation were general behaviour and brain antioxidant enzymes like superoxide dismutase, catalase, glutathione peroxidase, thiobarbituric acid reactive substances and nitrate levels. Histopathology of brain sections was done to quantify the degeneration. Results indicate that pretreatment with either nifedipine or Ginkgo biloba was bale to prevent an ischaemia-induced deficit of locomotion, ambulation and brain antioxidant parameters. Further, neuroprotective activity of nifedipine and *Ginkgo biloba* treatment was confirmed by the decrease in the number of dead cells in the hippocampal CA1 region. The findings suggest that nifedipine as well as Ginkgo biloba exhibited beneficial neuroprotective activity in global ischemia.

However, the recovery of the brain cells from the ischemic damage was found to be better with Ginkgo biloba pretreatment in comparison to nifedipine. The better effect with Ginkgo biloba may be due to co-existence of antioxidant activity with vasodilation property.

E16 Cognitive evaluation of losartan and enalapril in hypertensive & normotensive animal

Jayadev Sureddi*, Srinivasan J, Suresh B & Ramanathan M

Department of Pharmacology, J.S.S College of Pharmacy, Ootacamund, TN-643 001.

The present study was designed to evaluate the learning and memory in altered physiological state associated with increased blood pressure and activated RAAS in Wistar rats. Role of angiotensin in cognitive function was assessed by treatment with ACE Inhibitor (Enalapril) and angiotensin receiptor 1 antagonist (Losartan), Hypertension was induced in rats by Goldblatt renal hypertension model. The parameters used to assess the cognitive function were, radial arm

maze and passive avoidance step through behaviour tests. Since cholinergic dysfunction is correlated to cognitive impairment AChE level was measured.

The results indicated occlusive of renal artery increased the blood pressure and was found to be 194.0±1.6 mm of Hg. Hypertensive rats exhibited memory deficit in passive avoidance test as indicated by decreased IF_1 and IF_2 after 24 hrs & two weeks retention intervals respectively in comparison to vehicle treated normotensive animals. Similarly in Radial arm maze test, hypertensive rats exhibited working and reference memory deficits in relearning. Treatment of enalapril and losartan significantly reversed the observed memory deficit in renal hypertension rats. No influence of these drugs where observed in normotensive animals in radial arm maze performance. Decreased AChE concentration in hippocampus and frontal cortex region was observed in hypertensive rats, which indicate possible cholinergic deficit in these rats.

It can be concluded that hypertensive rats had a poor acquisition and impaired retrieval of the learned behaviour indicating a possible altered memory consolidation process and it was reversed with ACE Inhibitor and AT_1 receiptor antagonist which implies role of angiotensin in learning and memory process.

E_{17} Spirulina, a blue green algae prevents bone loss in ovariectomized rat model of osteoporosis

Nisha K.R*[1], Venkatesh P[1], Lakshmana M[1], Suresh Venktram[2].

1. Department of Pharmacology, Government College of Pharmacy, Bangalore- 560027,
2. Research and Development Centre, Zydus-Cadila Health Care Limited, Bangalore-560004.

Spirulina a blue green algae, was studied for its inhibitory effect on the progress of on bone loss induced by ovariectomy (OVX) model in rats. Ovariectomized rats were administered Spirulina at the doses of 500 and 1000mg/kg body weight twice a day orally for 18 weeks and compared with Sham operated animals. OVX control animals showed an increase in the urinary excretion of calcium, Phosphorus and L-hydroxyproline, which was significantly prevented in Spirulina treated rats. Phycocynin and gamma-linolenicacid of Spirulina inhibited the osteoclasts cells dose- dependently in in-vitro bone resorption studies, in the presence of 1α, 25 $(OH)_2$ D_3. This is further correlated with *in-vivo* histological studies as indicated by less TRAP-Positive multinucleated cells in Spirulina treated group as compared to ovariectomized control rats. The restorations of trabecular bone with less number of Tartrate Resistant Acid Phosphatase (TRAP) positive multinucleated osteoclasts were noticed in Spirulina treated rats indicating its inhibition of bone resorption. These observations are well correlated with Scanning Electron Microscopy and Quantitative X-ray analysis (SEM,-QXA), bone density results, and by bone bio- mechanical strength determined by bone impact and micro hardness test. In conclusion Spirulina treatment at the dose of 500mg/kg & 1000mg/kg b.w in adult ovariectomized rat model of osteoporosis showed desired effects on the inhibitors of bone resorption and stimulators of the bone formation, there by indicating a potential therapeutic usefulness as an anti-osteoporotic agent.

Osteoporosis; Ovariectomy; Spirulina; Bone histology; Bone Impact test;

E_{18} CNS activity of some new isatinoid compounds in mice and rats

N.R. Pani*, D.M. Kar, M. Banarjee

Univ. Dept.Phrm.Sciences, Utkal University, BBSR, Orissa, E-mail: niharpani@yahoo.com

Isatin derivatives have a wide range of pharmacodynamic activities as these contain indole nucleus, which is also present in several therapeutically potential natural products like reserpine, ergotamine, strychnine etc. Isatine derivatives are generally been associated with antimicrobial, antidepressant, anticonvulsant, anticancer and anti-inflammatory activities.

In the present study, primary aromatic amines i.e. p-chloro-aniline, p-bromo-aniline and aniline were subjected to reaction with isatin and then they were individually reacted with ethyl chloroacetate. The resulted three compounds were characterized by spectral and elemental analysis and evaluated for their CNS activity as well as anticonvulsant activity. Exploratory behavior (head dip test), muscle relaxant activity, Pentobarbitone sodium induced sleeping time and behavioral despair test, MES induced convulsant test, catalepsy test were evaluated by using suitable animal models. All the compounds of this series have caused decrease in exploratory behavioral pattern in head dip test and a reduction in muscle relaxant activity in rotarod test and catalepsy potential. The test compounds have very minimal effect on pentobarbitone induced sleeping time. The synthesized compounds have significant psychopharmacological activity. The most potent member among the synthesized compounds is 1-ethoxy carbonyl methyl-3-p-chloro anilino indole-23-dione.

All three newly synthesized compounds were found to possess equipotent psychopharmacological activity, less hypnotic & cataleptic potential in comparison to standard drugs. So, these compounds may be used as antipsychotic agents.

E19 Evaluation of the hypoglycemic and anti-oxidant activities of *Murraya koenigii* in streptozotocin-induced diabetic rats

M. Vijayakumar*, R. Govindarajan, G. M. M. Rao, Ch. V. Rao, A. K. S. Rawat, and S. Mehrotra

Pharmacognosy and Ethnopharmacology Division, National Botanical Research Institute, Lucknow 226 001

The aim was to investigate the hypoglycemic and anti-oxidant activities of the dried leaves of Murraya koenigii in streptozotocin-induced diabetic rats. We evaluated the hypoglycemic effects of three different single doses of the crude ethanolic extract and its fractions (water and n-butanol) in diabetic rats. After three hours of drug administration, fasting serum glucose, body weight, hepatic superoxide dismutase (SOD), activities, reduced glutathione (GSH), thiobarbituric acid reactive substances (TBARS) were estimated by standard method. In the three-hour dose response study, the crude ethanolic extract reduced the fasting serum glucose levels of the diabetic rats significantly at 150 mg/kg.

The water fraction demonstrated a dose dependent hypoglycemic effect in the diabetic rats whereas the n-butanol fraction increased the fasting serum glucose levels of the diabetic rats significantly within three hours after administration. Oral administration of the extract reduced the fasting serum glucose, hepatic TBARS and GSH level and significantly increased the hepatic SOD. The results indicate that the leaves of *Murraya koenigii* possess hypoglycemic and anti-oxidant properties.

E20 Action of *Asparagus racemosus* against streptozotocin -induced oxidative stress

R. Govindarajan*, M. Vijayakumar, G. M. M. Rao, Ch. V. Rao, A. K. S. Rawat, and S. Mehrotra

Pharmacognosy and Ethnopharmacology Division, National Botanical Research Institute, Lucknow 226 001

Streptozotocin -induced diabetic rats were treated with *Asparagus racemosus* extract as a hypoglycaemic agent. The effect was assessed on lipid peroxidation (LPO) and the antioxidant defense system in rat tissues. The increased levels of blood glucose in diabetes produce superoxide anions and hydroxyl radicals in the presence of transition metal ions which cause oxidative damage to cell membranes. The liver tissue showed an increased lipid peroxidation (LPO) in diabetic rats.

The treatment with *A. racemosus* lowered LPO in these liver tissues. The superoxide dismutase (SOD) activity increased in the liver in the diabetic group of rats probably to increase dismutation of superoxide anions. However, treatment with A. racemosus decreased SOD activity in the liver and was comparable to control rats. Catalase (CAT) activity was not significantly affected in any of the tissues in diabetic animals, however, CAT activity markedly increased in tissues with *A. racemosus* treatment. The changes such as the increase in kidney and heart SOD may be an adaptive response in order to neutralize superoxide anions. The increase in GSH activity in the tissue are in response to neutralize superoxide anions and to counteract oxidative stress in diabetes. The data indicate that *A. racemosus* may have potential use in lowering oxidative stress in diabetes.

E21 Antitumor effect of *bauhinia racemosa* against ehrlich's *ascites carcinoma* with reference to lipid peroxidation and antioxidant system in swiss albino mice

R. Sambath Kumar, M. Gupta, U. K. Mazumder, T. Siva Kumar, M.L.M. Vamsi

Department of Pharmaceutical Technology, Jadavpur University, Kolkata 700 032, India.

The petroleum ether extract of *Bauhinia racemosa* (Caesalpiniaceae) stem bark was evaluated for antitumor activity against Ehrlich's Ascites Carcinoma (EAC) bearing Swiss albino mice. The extract was administered at the doses of 50, 100 and 200 mg/kg body weight/day/mice for 14 days after 24 h of tumor inoculation. After the last dose and 18 h fasting mice were sacrificed. The present study deals with the effect of petroleum ether extract of *Bauhinia racemosa* (PEBR) on the growth of transplantable murine tumor, life span of EAC bearing hosts, hematological profiles and biochemical parameters such as lipid peroxidation (LPO), glutathione content (GSH), superoxide dismutase (SOD) and catalase (CAT) activities. Further, SGPT, SGOT, ALP, and bilirubin were estimated for hepato-renal function and metabolism. The PEBR showed significant ($P < 0.01$) decrease in tumor volume, packed cell volume and viable cell count and prolonged the life span of EAC tumor bearing mice. Hematological profiles reverted to more or less normal levels in extract treated mice. PEBR significantly ($P < 0.05$) decreased the levels of lipid peroxidation, while significantly ($P < 0.05$) increased the levels of GSH, SOD and CAT. The extract marginally altered serum enzymes and bilirubin. The results indicate that the petroleum ether extract of Bauhinia racemosa stem bark exhibited significant antitumor and antioxidant activity in EAC bearing mice

E_{22} Influence of beta adrenergic agonist and antagonists on inflammation and their interaction with Aspirin

Padgilwar S. S*[1], Indurwade N.H.[1], Biyani K.R.[1], Patil P.A.[2]

1. Department of Pharmacology, S.N. Institute of Pharmacy, Pusad.
2. Department of Pharmacology J. N.M.C. Belgaum.

Literature survey with respect to anti-inflammatory activity of adrenergic agonist and antagonists highlighted controversial reports. It is very difficult to conceive that both agonist and antagonists producing the anti-infiammatory effect. Therefore, the present study was planned to reinvestigate the influence of some β-agonist like terbutaline and specific as well as non-specifics β-blocker like atenolol and propranolol on acute model of inflammation in albino rats. The mention agonist and antagonists could be expected to influence the anti-inflammatory activity of NSAIDS. However these agents were also exploring for their possible interaction with aspirin commonly used NSAID.

As expected aspirin alone showed significant anti-inflammatory activity. Terbutaline, atenolol and propranolol in its therapeutic equivalent dose also showed significant anti-inflammatory activity in carrageenan induced rat paw edema method.

To study the possible interaction between aspirin and adrenergic agonist and antagonist, sub anti-inflammatory doses of aspirin was administered with terbutaline, atenolol and propranolol respectively Interaction results showed that terbutaline significantly potentiated the anti-inflammatory activity of aspirin in sub anti-inflammatory dose up to 3 hrs. While β-blockers when co-administered with aspirin in its sub anti-inflammatory doses could inhibit rat paw edema up to 1hr.

E_{23} Chronopharmacology of anthiypertensives in hypertensive patients with coronary artery disease

A.J.M. Christina, A. Ranjith Kumar, Preethi, N. Murugesh

Department of Pharmacology, K.M. College of Pharmacy, Madurai 625 107

The study summarises the circadian time based variation in the effect of antihypertensive drugs in hypertensive patients with coronary artery disease (CAD). The patients were treated with various antihypertensive drugs , Aspirin and vasodilators (nitrites). The blood pressure (B.P) was recorded at three different circadians times(CT) viz. CT0000 (6a.m), CT0800 (2p.m) CT1600 (10p.m). The time at which B.P(both systolic and diastolic) was minimum during a circadian and circaseptan (7 days) cycle was observed . This was studied in 50 inpatients. It was noted that maximal fall in B.P was at CT1600,(10P.M) in a circadian cycle and this fall was observed from the 2nd day of the circaseptan cycle with some drug combinations and from the 3rd day of the ciraseptan cycle with a few drug combinations. A salient and common feature observed was that in all the combinations which produced fall in BP from 2nd day of circaseptan cycle, B-blocker was a component. Hence it is concluded that beta receptor sensitivity may play a key role in controlling the B.P in hypertensive patients with CAD.

E_{24} A clinical evaluation of hypothalamic-pituitary-adrenal (HPA) axis activity in asthma patients treated with inhaled corticosteroids

P.V. Kasture, P.G. Phatak, Vijayaragavan.S*

Govt. College of Pharmacy - Karad

Inhaled corticosteroids are now popularly used because the inhaled route delivers medication directly to the lungs, the systemic availability of inhaled corticosteroids is less than that of oral corticosteroids. Nevertheless, persistent systemic exposure to exogenous corticosteroids even at low levels associated with the inhaled route may also have undesirable effects, such as suppression of (HPA) axis.

The suppression of (HPA) axis is usually identified as a decrease in the level of circulating cortisol. Such a suppression is a quantifiable indicator of the potential risk of systemic corticosteroids side effects.

Endogenous cortisol concentrations exhibit diurnal periodicity, at the morning 8AM the cortisol concentration have a standard value and is maximum at this time. As time passes the concentration gets decreased at 8PM it will be approximately half the value as in the morning. 8AM cortisol concentration are measured for identifying the suppression of HPA axis, because at this time the cortisol concentration is constant and comparable for all.

In the present study Asthma patients undergoing inhaled steroids treatment alone (not oral or I.V) are taken and measured for cortisol levels. The patients who were taking inhaled steroids of dose more than 1000mcg per day for a long period of time for control of asthma showed a decrease in cortisol levels. This study indicates that even inhaled corticosteroids also have side effects so that dose of inhaled steroids should be low when prescribed for a long period of time.

E25 *In-vitro* anti-cancer activity of citral

Syed Imam Rabbani*[1], Kshama Devi[2] and Amit Kumar Das[1]

*1. Krupanidhi college of Pharmacy, Bangalore 560 034

2. Department of Pharmacology, Al-Ameen college of Pharmacy, Bangalore 560 027.

The technological advancement of science has provided various comforts to mankind and has also resulted in entry of enormous substances as pollutants in human system. These agents can cause different types of disorders and diseases. Majority of these agents upon chronic exposure to human body has produced various types of cancers. Although there are varieties of anti-cancer drugs available, but still there is a search for those that causes minimum toxic effects. This is the prime reason to evaluate the majority of herbal drugs.

Citral is a major constituent of *Cymbopogon citratus* or Lemon grass oil. Lemon grass oil is commonly used as fold medicine to increase appetite, CNS stimulant, analgesic, anti-stress etc., but the anti-cancer potential of its major constituent citral was not found in literature. Hence the present study had evaluated the In-vitro anti-cancer activity of citral. The ability of the citral to decrease the fast proliferating germinating cells in Onion root tip *(Allium cepa L)*, Brine shrimp *(Artemia salina LEACH)* and Bengal gram *(Cicer arietinum)* was evaluated. In the present study Cyclophosphamide was used as standard anti-cancer drug to compare the potency of citral. The results show that citral in the tested doses has decreased the frequency of fast multiplying germinating cells and hence citral can be a potential anti-cancer drug.

E26 Prolactin analgesia - a comparative study

***R. Senthil Kumar, S. Jamuna Rani, S. Parvathavarthini, C. Prabakar Reddy G. Somasundaram**

Department of Pharmacology, Sri Ramachandra Medical College & Research Institute (D.U), Chennai.

It is a well-known fact that Prolactin, an anterior pituitary hormone plays a vital role in lactation. Apart from this Prolactin influences several physiological functions such as:

Maintenance of fluid and electrolyte balance, Contractility of vascular and cardiac muscle, Modulation of immune response.

To this list of interesting and versatile action of Prolactin adds also analgesia due to Prolactin.

This study was designed to study and compare the analgesia due to Prolactin when given as a drug, with analgesia due to Morphine and Ketorolac.

Ten groups of male mice were taken with ten mice in each group, five groups for testing analgesia using physical method and five groups, using thermal method. Morphine and Ketorolac were given intraperitoneally in doses of mgs/Kg body wt and 30 mcgs/Mice respectively. Prolactin was given subcutaneously in a dose of 200mcgs/kg body wt. Haffner's tail clip method was used for the physical method and Eddy's hotplate was used for the thermal method. The effects were studied at 0, 15 and 30 minutes interval. The reaction time was noted using a stopwatch (1/10 seconds).

The results were analyzed using students t test. The average reaction time were as follows

1. Morphine 16.2 seconds (physical method)- 24.4 seconds (thermal method)
2. Ketorolac 11.3 ———"——— 23.6 ———"———
3. Prolactin 6.9 ———"——— - 19.6 ———"———

There was also a significant synergism when Prolactin was co-administered with Morphine and when Prolactin was co- administered Ketorolac.

The obtained results clearly prove that Prolactin has got analgesic action, which are statistically well comparable with Morphine and Ketorolac.

E27 Modulatory effect of *Plectranthus ambonicus* on ethylene glycol induced nephrolithiasis in male albino rats

M.Alvin Jose*[a] S.Janardhanan [b], Ibrahim [b], S.S. Agrawal [a].

a. College of Pharmacy, New Delhi-17.

b. Cherraann's College of Pharmacy coimbatore.

Lithiasis is the frequent clinical problem in all over the world., Eventhough remarkable advances made in the treatment of renal tract stones ,cheap and effective measure to prevent the recurrence are not well established. *Plectranthus ambonicus* lour. (lamiaceae) commonly known in English as Indian borage is distributed throughout India,and used as a folk medicine for various illness including kidney stones. So in this study the extent of antilithiatic activity of the plant was studied by using ethylene glycol induced method.

In this study fresh juice of *Plectranthus ambonicus Lour.* was used and adult male albino rats of wistar strain weighing between 150-200g were used

as a experimental animal . Nephrolithiasis was induced by following the method of A.J.M. Christina et al. .that is feeding the animal with 1% ethylene glycolated water for 35 days. In the end of the study urine analysis and histopathology of kidney were done.

Urine analysis showed a significant elevation of calcium and oxalate level but insignificant protein in the lithiatic control group (G2) ,when compare to normal control (G1). In test group (G3) there was a significant reduction in all the parameters almost comparable with normal control, from the above results it is concluded that the plant inhibits the stone formation and histopathological studies of kidney provided solid evidence for the stone inhibitory activity of *Plectranthus ambonicus* Lour.

E_{28} Calcium channel blocking activity of a fraction of *Sarcostemma brevistigma* wight

P. Suresh Kumar*, K. Soni, C.A. Trivedi, A.C. Walekar and M.N. Saraf

Dept. of Pharmacology, The Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai-400098.

Sarcostemma brevistigma Wight (Family: *Asclepiadaceae;* Sanskrit: soma, Hindi: somlata) is a leafless, trailing shrub. This plant has been reported to have bronchodilatory and spasmolytic activities. The present study was undertaken to investigate the mechanism of the spasmolytic activity.

The twigs of the plant *S. brevistigma* were extracted with acetone and subsequently fractionated to obtain the fraction F-A. F-A was tested at the concentrations between ~ 6-70 µg/ml. F-A significantly inhibited KCl and oxytocin induced contraction of the isolated rat uterus *in vitro* in the Ca^{2+} containing physiological salt solution (PSS). The inhibitory effects were dose related. However, it failed to inhibit oxytocin induced sustained contraction of the isolated rat uterus in the Ca^{2+} free PSS. F-A also significantly inhibited histamine and acetylcholine induced contraction in the isolated guinea pig ileum and KCl induced contraction in the isolated guinea pig ileum and taenia coli in a dose dependent manner. F-A (40 µg/ml) significantly inhibited Ca^{2+} induced contraction in the isolated guinea pig taenia coli. Bay K 8644 (10^{-6} M), a calcium channel agonist, was found to revert the F-A induced inhibition of the Ca^{2+} induced contraction. These results indicated that F-A produced spasmolytic activity by interfering with the mobilization of extracellular Ca^{2+} as like calcium channel antagonists.

E_{29} Influence of spirulina on chronic fatigue syndrome induced changes in biochemical parameters

Suralkar S. R.*, Nipate S., Zambad S.P., Ghaisas M.M., Deshpande A.D.

Dept. of Pharmacology, Padm. Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune – 411 018.

Chronic fatigue syndrome (CFS) is a heterogenous disorder characterized by fatigue, neuropsychiatric symptoms. The etiology of CFS remained unclear. However, some studies have shown that oxidative stress plays a significant role in the pathogenesis. With the contemplation that CFS induced biochemical and pathological changes are the consequences of oxidative stress the present study was carried out to investigate the influence of spirulina treatment on CFS induced changes in immobility period and biochemical parameters.

The forced swimming-induced immobility in mice model was used to produce the CFS. The control and test groups were chronically forced to swim for 6 minutes session every day, for 7 days. Spirulina was administered intragastrically (40 mg/kg), 30 minute prior to the experiment in test group and immobility period was recorded. On 7th day blood was withdrawn to analyse the lipid peroxidase {LPO} superoxide dismutase {SOD} catalase, glutathione, blood glucose, serum cholesterol, triglycerides and serum proteins.

Daily administration of spirulina reduced the immobility period on each day as compared to respective controls. The daily spirulina treatment restored the levels of antioxidant enzymes and prevented the lipid peroxidation. The forced swimming induced changes in serum triglycerides, serum cholesterol, blood glucose & total protein were also attenuated by spirulina.

Thus, the reversal effect of spirulina on the CSF induced changes in the biochemical and oxidative stress parameters supports the etiological role of oxidative stress in the CFS induced changes and suggest the use of spirulina as antioxidant to ameliorate the biochemical and pathological complications of chronic fatigue syndrome.

E30 Evaluation of adaptogenic activity of *Cyanodon dactylon* aqueous extract employing biochemical approach in rats

S. Satyanarayana, V. Pallavi* and B. Krishna Murthy

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam – 530 003.

Cyanodon dactylon (C. dactylon) is widely used as a antiseptic, astringent, demulscent, diuretic, emollient, Cyanogenetic, tumors, headache and sores. It is also used in a number of Ayurvedic formulations for the treatment of Psoriasis. The present study aims in evaluating the adaptogenic activity of *Cyanodon dactylon* extract with the basic idea that its anti psoriatic activity might be due to its anti-stress activity. The evaluation of anti-stress activity was done by employing biochemical approach in rats.

In the case of stress corticosteroid synthesis which dependent on adrenal ascorbic acid increases as a physiological phenomenon with reduction in urinary ascorbic acid excretion. Similarly catecholamine levels change with changes in their urinary metabolite like vanillyl mandelic acid (VMA). The present work was conducted to find the influence of swim test (stress) on urinary ascorbic acid and VMA before and after treatment with and without treatment of aqueous extract of *C. dactylon* Urinary ascorbic acid and VMA were estimated by Roe and Kuether and Pisano's methods respectively. *C. dactylon* was administered to rats at doses of 30, 100 and 300 mg/kg body weight to find it dose response relationship in inhibiting stress induced changes in urinary ascorbic acid and VMA. The normal levels of ascorbic acid and VMA in 24 hr urine samples by each group were 62.06 mg/100 gm body weight and 169.41 mg/100 gm body weight respectively. In stress conditions the ascorbic acids levels decreased to 38.16 mg/24hr/100 gm body weight while VMA levels increased to 272.63 mg/24hr/100 gm body weight. It was observed that there was no change in VMA and ascorbic acid levels when *Cyanodon dactylon* was administered to normal rats indicating that it doses not interfere with basal levels. Similarly treatment with the extract along with the stress reversed the decreased urinary ascorbic acid and increased VMA levels to normal and the effect was dose dependent. It was also produced hydroxyl radical scavenging activity in *in-vitro* system conducted separately. The *in-vivo* results and *in-vitro* biochemical changes against swim stress provide evidence for its anti-stress (adaptogenic) activity in rats.

E31 Preliminary studies on acute and subacute toxicity of a hepatoprotective herbal formulation, HEPASRIL

R. Latha*, R. Murugeshwari, D. Chamundeeswari, V. Vaijayanthi, S. Uma Maheswari, C. Gandhimathi, J. Vasantha

Sri Ramachandra College of Pharmacy,
Sri Ramachandra Medical College and Research Institute (Deemed University), Porur, Chennai-116.

Hepasril a polyherbal formulation intended to use for liver disorders has been screened for toxic effects. For acute toxicity studies, Hepasril was administered orally in graded doses of 0.25-4ml/kg to the mice. For subacute toxicity studies, different doses of Hepasril (1.0.2.0and4.0ml/kg) were administered orally to the rats once daily for 30 days. Animals were observed for physiological and behavioural responses, mortality, food and water intake and body weight changes. All the animals were sacrificed on the 31st day and changes in organ weight and histology was examined. Biochemical studies were done in serum. No mortality was observed up to 4ml/kg of Hepasril in acute toxicity studies. Daily administration of as high as 4ml/kg of Hepasril did not result in any mortality or changes in gross behaviour, body weight, weight and histology of different organs - haematological parameters, and kidney function. However in higher doses i.e 4ml/kg the liver function was slightly altered compared to the normal group. The dose of Hepasril to produce significant hepatoprotective activity in rats, 0.25-0.55ml/kg is much lower than the doses used in the present study. Therefore such doses may be safe for daily administration without causing any serious side effects.

E32 A library based journal survey for identifying major geographical contributors of pharmacological research

Reddy PMK*, Tushar T, Ravindra KM, Nartunai G, Shewade DG, Ramaswamy S, Dkhar SA

Department of Pharmacology, Jipmer, Pondicherry 605 006

The geographical distribution of scientific publications has become an interest in recent times for those wishing to advance further in their field of interest. The objective of the study is to find major geographical contributors of pharmacological research based on retrospective study of research papers published in leading pharmacological journals during 2001.

A cross sectional retrospective library based search has been done involving the original research papers alone published in all the issues of the European Journal of Pharmacology, British Journal of Pharmacology, and Journal of Pharmacology and Experimental Therapeutics, from January to December 2001. Each article was screened for country of origin. When a collaborative research outcome between two countries or among more than two countries, then the article gives score 'one' to respective countries. They were computed and for ease only top 10 countries were taken, the rest were placed under others. The data of the above two methods were arranged in a tabular form to find scientific contribution of each country. From the above findings the number of divisions and number of countries contributed for each division were computed and ranked accordingly. The z test of proportions was used to find the significant difference between countries. $p<0.05$ (z value of 1.960 onwards) was considered statistically significant.

Country wise analysis revealed that authors from 46 countries contributed 1914 papers. Conversely, the 46 countries (alone or in collaboration) scored 2161 papers. Fig.1 indicates top ten countries (either alone or in collaboration with other countries) contributing % of papers of published in three journals. The USA came as the first nation by publishing 26%, next being Japan 15% and the third one is UK. The USA researchers contributed significantly higher number of papers in neuropharmacology ($P<0.0001$), and pharmacokinetics ($P<0.01$) . Japan researchers contributed highest number of papers for gastrointestinal pharmacology ($P<0.001$). UK published more papers in cardiovascular pharmacology. The USA, France, UK, Spain and Netherlands reported in ten out of eleven divisions. Developing countries like Brazil and India contributed 34 and 9 papers only.

E_{33} Pharmacological activity of Acorus calamus on central nervous system

A. D. Taranalli Manoj Chugh*

Department of Pharmacology, K.L.E.S's College of Pharmacy, Belgaum, Karnatka.

Learning and memory difficulties are the most frequent cognitive alterations in epileptic patients, with seizures which arise from the temporal lobes seem to be at particular risk.

Even lots of antiepileptic drugs have been reported to impair various cognitive processes. At this stage to have a safe and effective agent, one has to take shelter of herbal remedies.

Martis. G. and Rao A. reported that aqueous and alcoholic extracts of rhizomes of *A. calamus* reduce the severity of maximum electric shock induced seizures in rats. *Acorus calamus* is even reported to be having intellectual promoting properties. So in the lime light of its traditional use as a 'nootropic' agent, the present study was earned out to evaluate nootropic potential of Acute as well as Chronic treatment of *Acorus calamus* in electroshocked animals.

Active and Passive avoidance together provide a classic model for assessment of Cognitive performance. So hereby in our study two paradigms (a) Conditioned Active Avoidance Response (CAR), (b) Passive Avoidance task were employed to screen aqueous and alcoholic extract of *Acorus calamus* for 'nootropic' activity in electroshocked rats.

The memory improving effects of *Acorus calamus* were manifested as decrease in latency to reach SFZ (acquisition) and No. of mistakes (descents) the animals made in 15 min (retention) in Passive avoidance task.

Even in Conditioned Active Avoidance (CAR) extracts produced memory retention in more than 80% of rats previously subjected to electroshock treatment.

So aqueous as well as alcoholic extracts reversed MES induced deficits in acquisition and retrieval or in other terms Cognitive toxicity. So we propose the use of Acorus calamus in combination with Standard Antiepileptic drugs.

Further investigations are necessary to determine the exact phytoconstituent that is responsible for "NOOTROPIC" activity of *Acorus calamus* in epileptic patients.

E_{34} Anti-gastric ulcer activity of an ayurvedic brand and its comparison with ranitidine in shay rat

P.K. Panda, D. Pradhan, P. Sunita

University Department of Pharmaceutical Sciences, Utkal University, Vani Vihar

An Ayurvedic brand was tested for anti-gastric ulcer activity in Shay-Rat model. Oral dose of 50mg/kg reduced the ulceration in Shay rat with 100mg/kg the ulceration was completely absent . The anti-gastric ulcer activity of the selected Ayurvedic Brand (100Mg/Kg) was found to be equal to the effect produced by Ranitidine 10mg/kg. The reduction in gastric acidity was more with Cimetidine and the reduction in Peptic activity was more with the selected Ayurvedic Brand under test.

E35 *In-vitro* cytotoxicity and *in-vivo* acute toxicity studies on selected natural hydrogels as pharmaceutical excipients

Kulkarni G.T.*, Gowthamarajan K, Raghu C., Ashok G., Vijayan P., Kumar E.P and Suresh B.,

Department of Pharmaceutics, JSS College of Pharmacy, Rocklands, Ootacamund - 643 001 (TN)

Polysaccharide hydrogels constitute a structurally diverse class of biological macromolecules with a wide range of physicochemical properties. They also constitute important members of the family of industrial water-soluble polymers. They find application in Pharmacy as binders, disintegrants, suspending agents, emulsifying agents and sustaining agents. According to the International Pharmaceutical Excipients Council (IPEC), an excipient must have an established safety profile. Hence, in the present study, *in vitro* cytotoxicity studies on Vero and HEp-2 cell lines, and in vivo acute toxicity studies in rats were carried out to establish the safety of polysaccharide hydrogels from the seeds of *Plantago ovata* and *Ocimum basilicum*.

The *in vitro* cytotoxicity was determined by MTT and SRB assays on Vero and HEp-2 cell lines. In the in vivo acute toxicity studies, the effects of three different doses of hydrogels (100, 200 and 400 mg/kg body weight) on food and water intake, body weight, biochemical and hematological parameters were studied.

The results of *in vitro* studies did not show any cytotoxicity on both the cell lines used. In the in vivo acute toxicity studies, the hydrogels did not show any toxic symptoms at all the three dose levels selected. This establishes the safety of the selected hydrogels. Hence, they can be used as excipients in pharmaceutical dosage forms.

E36 Protective effect of co-administration of coenzymeQ10 and DL-a lipoic acid treatment on oxidative stress in gentamicin induced nephrotoxicity

Aman Upaganlawar * , Mamta Farswan, Shivkumar Rathod

Pharmacy Department, Faculty of Technology & Engineering, M. S. University of Baroda, Vadodara-390001

Free radical generation has been increasingly implicated in variety of pathological processes. A number of studies have demonstrated the ability of Gentamicin to generate radical species, which suggest that this process plays an important role in amino glycoside induced nephrotoxicity

The present study is designed to investigate the protective role of combined antioxidant Co-Q10 and á-Lipoic acid on oxidative status during Gentamicin induced nephrotoxicity in rats.

Administration of Gentamicin (80mg/kg/day,i.p) for 8days,produced increase in the level of Lipid peroxidation and decrease in the activity of antioxidant enzymes such as reduced glutathione(GSH), Superoxide dismutase(SOD) and Catalases (CAT).There was significant increase in serum Urea ,Createnine level and decrease in membrane bound enzymes such as Na^+ / K^+ATPase, Mg^{2+}ATPase, and Ca^{2+} ATPase suggesting nephrotoxicity and involvement of oxidative stress.

Administration Co-Q10 (10mg/kg/day,i.p) for 8 days and á-lipoic acid (25mg/kg/day,orally) for 8 days concomitantly with Gentamicin shows better protection than Co-Q10 and á-lipoic acid alone.

F1 Effect of pH and formulation additives on the transcorneal permeability of flurbiprofen across goat cornea

Sajeev C., Archna R., Jyothi Malika M., Saha R.N.*

Pharmacy Group, Birla Institute of Technology and Science, Pilani 333 031 (Rajasthan)

Most of the topically applied drugs have to enter the eye through the corneal route and the epithelial and stromal layer act as barrier to transcorneal permeability for variety of drugs, both hydrophilic and lipophilic. The present study was aimed at investigating the *in-vitro* transcorneal permeability of flurbiprofen in excised goat cornea using modified Franz diffusion cell. Effect of buffer type (phosphate, citrate-phosphate and citrate) and different pH of phosphate buffer and unbuffered media on the permeability of the drug was investigated. Effect of formulation excipients like, sodium chloride (0.9% w/v), thiomersal (0.004% w/v), benzalkonium chloride (0.01% w/v), chlorobutanol (0.5% w/v), phenyl mercuric nitrate (0.002% w/v), disodium edetate (0.01% w/v), methyl p-hydroxy benzoate (0.04% w/v) and propyl p-hydroxy benzoate (0.02% w/v) on the corneal permeability of flurbiprofen was also studied.

Results of *in-vitro* trans corneal permeability studies of flurbiprofen indicate that the permeability of the drug from simple aqueous drop was very low with only 33.2 ± 2.7 µg of the drug permeating in 120 mins with a calculated flux of only 0.5842 µg/min cm^2, whereas in case of market formulation (OCUFLUR) the permeability was considerably enhanced with 98.1 = 5.4 µg permeating in 120 mins and a flux of 1.7028 µg/min cm2. Replacing the aqueous vehicle with different buffers namely, phosphate buffer (pH 7.4), citrate buffer (pH 6.6) and citrate-phosphate buffer (pH 7.0) resulted in statistically significant ($p<0.05$) increase in the corneal permeability of the drug. The vehicle pH under both buffered and unbuffered conditions was also found to effect the transcorneal permeability of the drug. In case of phosphate buffer of varying pH, statistically significant ($p<0.005$)decrease in the corneal permeability for flurbiprofen was observed with increase in pH of the vehicle. A similar phenomenon was observed with unbuffered solutions of varying pH. Studies on the effect of formulation additives on the transcorneal permeability revealed that the above formulation excipients in the concentration used increased the rate of corneal drug permeation by statistically significant ($p<0.05$) amount. A statistically significant ($p<0.05$) increase was also observed in case of formulation prepared using NaCl.

Thus, it can be concluded that transcorneal permeability of flurbiprofen decreased with an increase in pH of the media. Commonly employed ophthalmic additives significantly increased the rate of corneal permeation but with a high corneal hydration between 83 to 86%, indicating the adverse effects of these agents on the corneal cell structure and its integrity.

F2 Bidirectional transport of Paclitaxel in Sprague-Dawley rat ileum: R Role of P-glycoprotein

Varma MVS* and Panchagnula R

Department of Pharmaceutics, National Institute of Pharmaceutical Education and Research, Mohali, Punjab.

Drug efflux pumps like P-glycoprotein (P-gp) are recognized to posses functional role in determining the pharmacokinetics of drugs administered by peroral route. P-gp recognizes a large number of drugs as foreign material and efflux them. The purpose of the present work is to investigate the functional role of P-gp in limiting the intestinal permeability of Paclitaxel (PCL).

Sprague-Dawley rat illeum was used for these ex vivo permeation studies as per the approved protocols, by Institutional Animal Ethics Committee, NIPER. Intestinal drug transport was measured by everted sac technique similar to those described previously (Tian et al., 2002). Intestinal mucosa was bathed on the (A) *pical* and (B) *asolateral* surfaces with 10ml and 3ml of Ringers buffer saline (RBS) pH7.4, respectively. Mixing on the A surface was provided by continuously oxygen lifting system. For bidirectional transport studies, PCL (25mM) with ^{14}C-PCL was added to the A or B surface with or without verapamil (200µM) or propranolol (300µM). The amount of ^{14}C-PCL permeated was determined by liquid scintillation counting.

PCL bidirectional transport is found to be highly polarized with more permeability in BàA direction ($P_{app,B}à_A.10^6$cm/sec = 8.9+0.6) and less permeability in AàB direction ($P_{app,A}à_B.10^6$cm/sec= 0.4+0.1)(oneway ANOVA $p<0.01$). The calculated efflux ratio ($P_{app,B}à_A$ / $P_{app,A}à_B$ = 15.9+2.1) showed that the BàA flux is about 10 folds higher that that of AàB. Permeability of PCL in the presence of propranolol did not change ($p>0.05$), while in the presence of verapamil, a P-gp inhibitor, efflux ratio practically reduced to ~2 ($p<0.01$) due to increase in $P_{app,A}à_B$ and decrease in $P_{app,B}à_A$. Increase in absorptive transport and decrease in secretary transport by verapamil but not by propranolol clearly indicate that the PCL intestinal absorption is significantly hindered by P-gp.

Results of ex vivo everted sac bidirectional permeability studies indicated that P-gp plays a significant role in limiting oral absorption of PCL. Modulation of PCL bidirectional transport by P-gp inhibitors may significantly improve the intestinal absorption.

F3 Absolute oral bioavailability and dose proportional pharmaco kinetics of DRF 6196, a novel oxazolidinone in Swiss Albino Mice*

Ravikanth Bhamidipati[a*], Prajakta V. Dravid[a], Biju Benjamin[a] N.V.S. Rao Mamidi[a], C. Prasad Narasimhulu[b] C.V. Laxman Rao, Jagattaran Das[b], Ramesh Mullangi[a] and Nuggehally R. Srinivas[a]

a. Drug Metabolism and Pharmacokinetics, bDiscovery Chemistry, Discovery Research, Dr. Reddy's Laboratories Ltd., Miyapur, Hyderabad-500 049, A.P

DRF 6196, a novel oxazolidinone analog, has shown excellent in vitro and in vitro activity against several Gram-positive organisms. Here in we report, the absolute oral bioavailability and dose proportional oral pharmacokinetics of DRF 6196 in male Swiss Albino Mice (SAM).

HPLC method was developed to determined the concentrations of DRF 6196 in mouse plasma. In a parallel study design, single dose oral pharmacokinetic evaluation was carried out at 10.30 and 100 mg kg. dose levels in male SAM (n=10 per dose). Single dose intravenous (i.v) pharmacokinetics was performed in male SAM (n=10) at 10 mg /kg. Following oral and i.v. doses, sparse blood samples were collected via retro-orbital plexus. The composite plasma concentration versus time data was subjected to non-compartmental analysis for generating pharmacokinetic parameters.

DRF 6196 was well absorbed across the tested dose range, reaching maximum plasma levels within 0.5 h after oral administration. Following single oral doses 10.30 and 100 mg/kg. ratios of mean C_{max} and AUC_{0-z} values were 8.41:15.32:77.74 and 3.02:9.29:25.76, respectively. Both the values increased proportional to dose increments (1:3:10). The terminal half-life ($t_{1/2}$) was found to be similar following oral and i.v. administration. Oral bioavailability was found to be 58-96% across tested doses.

DRF 6196 exhibits linear pharmacokinetics and good bioavailability in mice. DRL Publication No. 155-A

F4 Regional gastrointestinal permeability of anti-tubercular drugs (alone and their combinations) in the rat

T.T. Mariappan[1*], Sukhjeet Singh[2], K.C. Jindal[2] and Saranjit Singh[1]

1. Department of Pharmaceutical Analysis, NIPER, Sector 67, S.A.S. Nagar, Punjab

2. R & D Centre, Panacea Biotec Ltd., Lalru, Punjab

Recently, we carried out and reported the segmental gastrointestinal permeability studies on rifampicin (R) and isoniazid (H), which proved that novel fixed dose combination (FDC) products of R and H can be easily developed by releasing rifampicin in stomach and isoniazid in distal intestine as the former is well absorbed through stomach and duodenum and the latter is better absorbed through intestine. These formulations are expected to be devoid of any decomposition of rifampicin in acidic conditions of stomach when present along with isoniazid.

As the therapy of tuberculosis involves administration of other anti-tubercular drugs, like pyrazinamide (Z), ethambutol (E) and ofloxacin (O), it was felt necessary to study the segmental gastrointestinal permeability of these drugs and the influence of these drugs on the permeability of each other and on other anti-tubercular drugs including R and H. The purpose of this study, therefore, was to determine the permeability behaviour of Z, E and O alone and two drug combinations of R+Z, R+E, R+O, H+P, H+O and Z+O in different segments of the GIT of rats.

The permeability was determined in stomach, duodenum, jejunum and ileum using in-situ ligated loop technique. The drug concentrations for R, H, Z, E, and O were 2.4, 1.2, 6, 4 and 2.4 mg/ml, respectively. The concentrations of the drugs were calculated based on the human dose of each drug, gastric volume in humans in the fasted state (250 ml) and the average weight of the animals (~250 g). The total drug disappeared from the loop was determined by deducting sum of the amount present in the loop and the mucosa from the initial amount injected. All the drugs except E were analyzed by a validated HPLC method and E was analyzed by a quantitative LC-MS-MS method.

Pyrazinamide was found to be well absorbed from all the segments of intestine. E showed good absorption through duodenum and jejunum. O was well absorbed from duodenum. Combinations of R+Z and R+O did not show any influence on the permeability of each other. The permeability of E in R+E combination was not affected but the permeability of R was decreased in ileum as compared to single drug administration. This could be attributed to the suppression of the solubility of R by E, as a result of lowering of pH. The pH of the R solution was reduced from 7 to 4.8 on addition of E. R was found to have lower solubility at pH 4.8 than 7.0. Combinations of H+P, H+O and Z+O did not show any influence on the permeability of each other.

F5 Clinical concept in con-current drug therapy

A. A. Machcha*, P. S. Kashid, A. D. Shinde, S. B. Bhise

Budhawar Peth, Karad 415 110, Satara District

Drug interaction result from the use of two or more drugs, in a specific disease condition. This may

lead to enhanced or diminished effect and may be useful or harmful. The useful drug interaction is illustrated by synergistic combination of drugs, while harmful drug interactions are, unfortunately more numerous.

A new symptom appearing during treatment with a drug may be due to two reasons one is disease and other is drug, this can be perplexing enough. But if the patient is receiving several drugs and two or more drugs are capable of causing the same new symptom as the underlying disease, or if two drugs in concert, elicit symptoms that would not otherwise appear.

The pharmacokinetic parameter volume of distribution is a proportionally constant that relates drug concentration in a reference fluid, typically plasma, to the amount of drug distributed throughout the body.

Drugs that distribute widely to tissues will have large volumes of distribution and low plasma concentration relative to the dose administered, where as drugs that are highly bound to plasma protein or do not readily enter cells will have low volumes of distribution and high plasma concentration relative to the administered dose.[1]

Due to concurrent drug therapy , two drugs such as Digoxin and Quinidine in congestive cardiac failure and in cardiac arrhythmia respectively. Here because of drug interaction the change in distribution was occurred by decrease in tissue binding. Since here Quinidine decreases the volume of distribution of Digoxin along with decrease in renal clearance but does not appear to alter plasma protein binding.

This drug interaction in the body due to concurrent drug therapy affect not only pharmacokinetic but pharmacodynamic. The pharmacokinetic parameters such as, renal clearance, volume of distribution, plasma half-life, protein binding are also get affected.[2]

Multiple drug therapy should never be employed without proof that a therapeutically equivocal combination is definitely harmless.

F_6 Effect of pH and formulation additives on the transcorneal permeability of flurbiprofen across goat cornea

Sajeev C., Archna R., Jyothi Malika M., Saha R. N.*

Pharmacy Group, Birla Institute of Technology and Science, Pilani –333 031 (Rajasthan)

Most of the topically applied drugs have to enter the eye through the corneal route and the epithelial and stromal layer act as barrier to transcorneal permeability for variety of drugs, both hydrophilic and lipophilic. The present study was aimed at investigating the in-vitro transcorneal permeability of flurbiprofen in excised goat cornea using modified Franz diffusion cell. Effect of buffer type (phosphate, citrate-phosphate and citrate) and different pH of phosphate buffer and unbuffered media on the permeability of the drug was investigated. Effect of formulation excipients like, sodium chloride (0.9 % w/), thiomersal (0.004 % w/v), benzalkonium chloride (0.01 % w/v), chlorobutanol (0.5 % w/v), phenyl mercuric nitrate (0.002 % w/v), disodium edetate (0.01 % w/v), methyl p-hydroxy benzoate (0.04 % w/v) and propyl p-hydroxy benzoate (0.02 % w/v) on the corneal permeability of flurbiprofen was also studied.

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Thus, it can be concluded that transcorneal permeability of flurbiprofen decreased with an increase in pH of the media. Commonly employed ophthalmic additives significantly increased the rate of corneal permeation but with a high corneal hydration between 83 to 86 %, indicating the adverse effects of these agents on the corneal cell structure and its integrity.

F_7 Pharmacokinetic evaluation of potent anti-inflammatory, analgesic aryl amino thiazole-5 acetic acids derivatives"

Vanaja K.*[1], Shobha Rani, R. Hiremath[2] and Hemanth K. Jajoo[3]

1. Visveswarapura Institute of Pharmaceutical Sciences. Bangalore.
2. Al-Ameen College of Pharmacy, Bangalore.

3. Astra Zeneca Research Foundation, Bangalore.

Rational drug discovery requires an early appraisal of all factors impacting on the likely success of a drug candidate in the subsequent preclinical distribution, metabolism, excretion and pharmacokinetics (ADME) has developed established *in-vitro* and *in-vitro* methodologies. Aryl acetic acids are well known clinically as antinflammatory and analgesic drugs. Thiazole-5-acetic acids with aryl substitution at position c-2 were previously reported to have potent anti inflammatory and analgestic properties. Two derivation viz., Methyl 4-(4-chloro phenyl)-2- phenlyl amino) thiazole acetate (MTA) and Ethyl 4-(4-chloro phenyl) 2-phenyl amino) thiazole acetate ETA) were synthesized and screened for analgesic and anti-inflammatory activity. A chromatographic method was developed by using methanol: ammonium acetate (0.05 M, pH 5) at a flow rate of 1 ml/min with UV detection at 254 nm for MTAmm ETA and Ibuprofen. Retention time was observed at 12.86 (MTA), 10.63 (ETA) and 14.35 (Ibuprofen). Samples were extracted by precipitating plasma proteins and recovery was > 80% in case of all drugs. Calibration curve was linear over a concentration range of 1.30 mg ml (MTA), 0.5-30 μg/ml (Ibuprofen). Pharmacokinetic (PK) study was carried for these newly synthesized drugs and compared with Ibuprofen. PK parameters studied were $C_{max,}$ $t_{max,}$ K_e and $t_{1/2,}$ $AUC_{(0-0)}$ and $AUC_{(0-\infty)}$

F_8 HPLC monitored study of venlafaxine metabolism using microbes

M. Vidyavathi*, K.V.S.R.G. Prasad, J.V. Vidya Sagar, D.R. Krishna

Institute of Pharma Technology, Sri Padmavati Mahila Vishwavidhyalaya, Tirupathi AP

Venlafaxine is a novel antidepressant, acts by inhibition of the reuptake of presynaptic noradrenaline and serotinin. It is known that microbial model systems can be employed as good predictors of mammalian drug metabolism. For this study a rapid, specific and accurate HPLC method was developed to characterize venlafaxine and its metabolites after incubation with some microbial cultures.

Different organisms screened and studied for venlafaxine metabolites (*Proteus vulgaris* (NCIM 2027). *Pseudomonas aeruogenosa* (NCIM 2053), *Cunninghmela elegans* (NCIM 689), *Sacchromyces cervesiae* (NCIM 3090). The experiments were carried out using their respective media. The HPLC system consisting of LC-8A solvent delivery module and SPD - 10 AVP UV- Visible spectrophotometric detector and Wakosil 115c-18rs-100a. 5UM.4.6X 250 mm SScolumn was used fort he analysis. Sensitivity was set 0.001 a.u.f.s. Mobile phase consisting of 0.01M Sodium phosphate pH03.8 and acetonitrile mixture (75:25 v/v) was used at a flow rate of 1.0ml/min. Elute was monitored using a UV/VIS detector set at 200 nm.

The developed HPLC method has shown a linear response over the concentration range of 0.5ugm/ml. A good accuracy (98.15%) was achieved for all quality controls with intra-day and inter-day variation coefficient less than 8%. No endogenous interfering peaks were visible with blank culture media. Finally the rapid HPLC method was developed for estimation of the venlafaxine metabolites in microbial biotransformation studies.

In the HPLC analysis of the culture extracts of selected organisms, the obtained peaks were almost identical with those seen in control and blank samples. No metabolites have been found using all the four organisms.

F_9 Quantitative estimation of levocetirizine from human plasma by RP-HPLC : application to pharmacokinetic study

S. I. Bhoir*, P.M. Saji, S. A. Jadhav, N. R. Lad and A. M. Bhagwat

CB Patil Research Center for Chemistry and Biosciences, Baidas Hall Building, Vile Parle (W), Mumbai - 400 056

A sensitive and selective high performance liquid chromatographic method has been developed for Levocetirizine, a piperazine derivative. The analyte was extracted with 1.0ml of 1M citrate buffer (pH -5) and 5.0ml of chloroform, followed by vortex, evaporation, dissolution and injection into a reversed -phase column. Chromatographic separation is performed on a Waters Microbondapak C18, 300mm X 3.9mm I.D., 10mm particle size column using a mobile phase made of acetonitrile and 0.01M ammonium acetate buffer (45/55 : v/v) at a flow rate of 1.0ml/min. Detection is achieved by UV-Vis detector set at 230nm. The assay performance was evaluated through analysis of variance and of regression with usual validation design. The method detects 32ng/ml and shows a linear response with a coefficient of variation from 50 to 900 ng/ml. It is easy, robust and seems well suited to therapeutic drug monitoring.

F_{10} Bioequivalence study of mirtazapine in healthy india male volunteers

R. T. Sane **, Sasikumar Menon, Pravin Patil*, Shafi Inamdar, Amol Pawar

Therapeutic Drug Monitoring Lab, Sion (E), Mumbai - 22

Mirtazapine is nonadrenrgic and specific serotonergic antidepressant (NaSSA) which has predominantly been evaluated of major depression. The drug had equivalent efficacy to tricyclic antidepressants.

The objective of present study was to evaluate pharmacokinetic parameters of mirtazapine of the test preoparation with the reference prepatation, MIRTAZ as 30 mg tablets. The study was conducted on twelve healthy. Indian human males. The drug from plasma was estimated by using a reverse phase HPLC method using an UV detector at 293 nm.

The mean values of the various pharmacokinetics parametera such as C_{max} ln C_{max} $T._{max}$ AUC $_{0-t}$, ln AUC_{0-t}- AUC $_{0-x}$,K_{el} and T1/2 were calculated and the data ontained was subjected to statistical analysis. ANOVA was applied to the various parameters and no significant variation was observed with subject period and treatment as variables. When 90° confidence interval was calculated it was found within the prescribed limit of 80%-120% for untransformed and 80%-125 for logreansformed parameters. Thus the test preparation MIRTAZAPINE was found to be bioequivalent to the reference preparation. MIRTAZ containing 30 mg of martapine

F_{11} Influence of diosmin on the bioavailability of diclofenac sodium in healthy volunteers

M. Soma Shekar*, A. Venkatesham, M. Sripal Reddy, K. Rajanarayana, J. Vidya Sagar, D. R. Krishna

University College of Pharm Sciences, Kakatiya University, Warangal - 9.

Flavonoids inhibit a number of enzymes in the body, which include oxidative metabolic enzymes. *In vivo* and *in vitro* studies have shown that flavonoids can enhance or inhibit the activities of certain CYP isoenzymes. The interaction of Diosmin (3',5,7 - trimethoxy - 4' - methoxyflavone 7 - rutinoside) on CYP 2C9 was studies using Diclofenac as substrate.

The first part of the study consisted of oral administration of two tablets of 50 mg of diclofenac sodium alone and blood was sampled from antecubital vein. Blood samples were obtained at intervals of 0, 0.5, 1,2,3,4,5,6,7 and 8 hours and urine voided during 0-4 and 4-8 hours respectively was collected after the administration of diclofenac sodium. After washout period 500 mg of diosmin was concomitantly administered with 100 mg of Diclofenac. Blood and urine samples were collected at different time points as stated above. Diclofenac is serum and urine are quantified by standard HPLC method.

There is no significant difference in the t_{max} $t_{1/2'}$ CL/f and Vd/f values of diclofenac sodium serum levels in the volunteers upon diosmin concomitant treatment. There is a significant increase in both AUC $_{(0-8h)}$ and AUC $_{(0-\alpha)}$ by 54.68% and 65.31% respectively of diclofenac sodium. Similarly there was a significant enhancement in the C_{max} (37.24%) following concomitant administration. Urinary excretion of unchanged diclofenac was increased.

Increased bioavailability of diclofenac may be due to inhibition of CYP2C9 and P-gp by Diosmin.

F_{12} Bioequivalence study of rabeprazole sodium in healthy human volunteers

Mandal U., Ganesan M., Jayakumar M., Senthil Rajan D*, Nandi S., Pal T.K.

Bioequivalence Study Centre, Department of Pharmaceutical Technology, Jadavpur University, Kolkata – 700032.

Newly developed proton pump inhibitor Rabeprazole sodium has been reported to have more beneficial effects in the treatment of peptic ulcer than the earlier ones. The pharmacokinetic parameters (C_{max}, AUC_0-$_t$, t_{max}) of this drug have been evaluated to compare the single dose (20 mg) bioavailability of Rabeprazole sodium contained in a Test dosage form with a Reference product of the drug at same dose. High performance liquid chromatography (HPLC) coupled with U-V detector set at 280 nm has been used to determine plasma concentration of rabeprazole in 12 healthy human volunteers and the pharmacokinetic parameters of the Test and Reference product were compared to establish the Bioequivalence of the Test dosage form as per DCGI (Drug Controller General of India) guidelines. The HPLC method has been validated over a linear range of 20-480 ng/ml from plasma. The minimum quantifiable concentration was set at 10 ng/ml (% CV < 10%). By comparing AUC_0-$_t$ the relative bioavailability of Test preparation has been found to be 100.88% of that of reference preparation.

F_{13} Therapeutic efficacy of sustained action nicotinic acid preparation on patients with hyperlipoproteniam

R. Saraswathi, S. Thanikachalam, B.S.R. Raddy, Abbay, Abbaypharam, P. Bak

KMCH College of Pharmacy, Kovai Estate, Coimbatore 641 035

We aimed to determine whether nicotinic acid in low doses of tablets 5 and 20 mgs thrice a day and TDDS (20mgO.D.) has therapeutic efficacy. The tablets were prepared as per pharmaceutical standard and TDDS were prepared using NS gel as a reservoir. The invitrio invivo studies were very satisfactory. So the formulations were given to human patients. After getting permission from ethics committee as per Helsinki declaration 100 patients with hyperlipoproteinemia were recruited between Jan 2000 to June 2001 in the age group of 39 to 70 years. The inclusion criteria of the patients were high serum total cholesterol, serum triglyceride serum LDL. and low serum HDL. The exclusion criteria were the patient with known history of

hepatic damage. The trial was open case control randomly studies in the department of clinical chemistary of participating in university clinics with standard methods. Fasting blood test was performed to measure the concentration of total chlolesterol, HDL, LDL, TGL, VLDL. The primary outcome was significant reduction in total cholesterol (20%) TGL (33%), LDL (33.73%). VLDL (30%), and increase in HDL (16.35%) The secondary outcome of NA transdermal patch administration was reduction in TC (32%), TGL (50%), LDL (39%), VLDL (47%), improvement in HDL (32%). The p value was less than 0.05%. The SR low dose of NA as patch releases the drug constantly and maintains the drug concentration in plasma for 12 hrs tapering down to first order kinetics. So it is concluded that NA in low doses can be given as SR transderma patch as a prephylactic and therapeutic drug to the patients with risk factors of artherscleroSis.

F14 Effect of two different types of breakfast on bioavaibility of Lamotrigine in healthy human male volunteers.

Sharma Charu*, Saha Nilanjan, Ojha Shreesh, Debey Tatan, Kumar Harender

Nabi Karim Jhande Walan Road, Pahar Gani, Delhi 110 055

Lamotrigine is a newer antiepilepic drug used in partial seizures. It has narrow therapeutic index drug so the achieved blood levels of the drug is closely related to the therapeutic efficacy. The bioavailability of lamotrigine is effected by food hence the study compared the effect to two types of India breakfast on the bioavailability of lamotrigine.

A randomized, open-label, balanced, three treatment, three period three sequence, single dose and crossover pharmacokinetic study to asses the healthy male volunteers. A single dose of lamotrigine was administered at three occasions, after a overnight fasting, after a north-Indian diet, and after a south Indian diet, Serial blood samples were collected upto 24.0 h post dose. Plasma lamotrigine concentration were determined with a validated HPLC method.

A statistically significant decrease in rate and extent of absorption was found with north Indian diet when compared with overnight fasting. South Indian diet also decreased the rate and extent of absorption but not to a significant level

North Indian diet decrease the bioavailability of lamotrigine as compared to both fasting and south Indian diet.

F15 Absorbability of an anti-ischemic and anti-hypertensive agent CDRI-93/478 in rats

J. Lal* and R. C. Gupta

Pharmacokinetics & Metabolism Division, Central Drug Research Institute, Lucknow

CDRI-93/478, a potent anti-ischemic and anti-hypertensive agent, is in advanced stage of preclinical trials. Its absorption was evaluated using both *in-situ* (closed-loop method) and *in-vivo* (portal-venous difference) approaches in male *Sprague-Dawley* rats.

In *in-situ* absorption study at pH 2.6 and 7.4, a 10-cm rat intestinal loop was prepared and was washed with perfusion solution. The perfusion solution was then expelled and compound solution (10µg/ml) was circulated into the system and samples were collected upto 30 min. In *in-vivo* experiment, the absorption kinetics was evaluated using portal - venous blood samples were collected upto 8h. The samples were assayed using validated HPLC method. The concentration-time data were subjected to WinNonlin software to determine the rate of abortion as well as other pharmacokinetic parameters.

The rate of absorption from *in-situ* experiment was found to be 0.66h^{-1} at pH 7.4 whereas it was negligible at pH 2.6 (0.015 h^{-1}). In *in-vivo* study, a portal and venous level peaked at 0.75 h and 1h and showed double peak phenomenon. The compound was absorbed at an absorption rate of 0.54 h^{-1}, which was comparable with the *in-situ* study at pH 7.4. The portal levels were higher than the venous level upto 4h and became almost equal at subsequent time-points indicating rapid absorption.

F16 Involvement of CYP 3A4 in the metabilism of CDRI-80/574, an antilipidemic drug

Pratima Srivastava* and R.C. Gupta

Pharmacokinetics and Metabolism Division, Central Drug Research Institute, Lucknow-1

CDRI- 80/574 (3 - β hydroxy-5, 16 pregnadiene-20-one-DHP), a new orally effective antilipidemic agent is in advanced stages of preclinical trails. However, the pharmacokinetic data revealed its low systemic bioavailability. One of the possible reasons behind the same may be its rapid metabolism.

Studies were carried out to see the in vitro metabolic profile of CDRI-80/754 in the hepatic and extra hepatic (intestinal wall, intestinal microvilli) issues as well as fresh fecal matter (microbes), and to ascertain the involvement of specific CYP 450 isoforms in the metaboish using specify *in vitri in vivo* inhibitors / inducers.

Hepatic S9 metabolism of CDRI -80/574 resulted in appearance of two metabolites (wavelength 248nm). The rate of conversion from the parent drug to the metabolites was 80% at 60 min. Extra hepatic tissues (intestinal wall and microvilli) as well as fresh fecal matter (microbes). having low CYP450 activity did not depicted a rapid decrease in the initial levels. The metabolism was found to be confined to the microsomal fraction and was enzymatic in nature.

Ketoconazole and Diltiazem (specific inhibitors of CYP 3A4) significantly (>99%) inhibited the CDRI-80/574 metabolism this was correlated with the increased bioavailability of CDRI-80/574, when rats were pretreated with grapefruit juice (specific inhibitor of CYP 3A4). Phenobarbitone (specific inducer of 3A4 isoform) was found to induce the metabolism.

F_{17} RP-HPLC determination and Pharmacokinetic Evaluation of Leflunomide as its metabolite from human volunteer

R.T. Sane, Sasikumar Menon, Abhijeet Deshpande*, Mandar Mote, Sangeeta Parab**

Therapeutic Drug Monitoring Lab, Plot - 194, Scheme 6, Sion (E), Mumbai 22

Leflunomide is a potent immunosuppressant that inhibits both T-cell and B-cell activity, likely through an inhibition of lymphocyte tyrosine kinase activity. The immunosuppresant activity of leflunomide is expressed after conversion to its pharmacologically active metabolite A 771726. The current work describes a method for determination and pharmacokinetic evaluation of leflunomide as its metabolite from human volunteer using HPLC system with UV detector (Jasco).

Leflunomide as its metabolite was extracted from plasma in basic condition using ethyl acetate as extracting solvenet. Separation of leflunomide as its metabolite was carried out on C_{18} column using 0.05 M Ammoniun acetate: Acetonitrile as mobile phase. Detection was carried out using UV detector at 280 n,. The liner detector response was observed for leflunomide as its metabolite between 0.05 µg/ml to 8 µg/ml. Method developed was validated for the parameters of linearity, accuracy, precision, stability and specificity. Hence developed method can be applied for the determination of pharmcokinetic parameters of leflunomide as its metabolite.

The study was performed to evaluate the pharmacokinetic parameters of leflunomide as its metabolit in human male volunteers, using formulations manufactured by two different manufacturers. Parallel study was designed using 24 human volunteers who were divided in two groups (each group containing 12 volunteers). Each group received one formulation on one occasion. Blood samples were withdrawn at 0, 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 24, 48, 72, 96, 144, 192, 240, 360, 480, 600 and 720 hours and collected in centrifuged tubes containing 0.1 ml of 10% EDTA as anticoagulant. Plasma was separed and stored at -20°C until analysis by HPLC.

C_{max} following oral administration of two different preparations were found to be 4.15 ± 0.33 µg/ml and 4.34 ± 0.32 µg/ml. T_{max} of two preparations were found to be 10.67 ± 1.58 hrs and 9.17 ± 0.93 hrs. $AUC_{(0-t)}$ of both preparations were found to be 1163.83 ± 156.45 µg/ml x hr and 1036.27 ± 113.68 µg/ml x hr. $AUC_{(0-\infty)}$ follwoing oral administration of two different preparations were found to be 1378.06 ± 226.46 µg/ml x hr and 1120.25 ± 136.00 µg/ml x hr. The elimination rate constants (K_{el}) for both preparations were 0.009 ± 0.006 hr and 0.008 ± 0.003 hr and elimination half lives were 21012 ± 31.32 hrs and 132.58 ± 19.23 hrs.

F_{18} Bioequivalence evaluation of a combined dosage form containing Metformin and Pioglitazone

Ajithlal. T*, Vasudevan. M, Ravichandran M, Nagarajan. J.S.K. and Suresh. B

Bioequivalence Centre, Centre for Advanced Drug Research and Testing, J.S. S. College of Pharmacy, Ootacamund

A comparative bioequivalence evaluation between two commercially available combined formulations of Metformin SR plus Pioglitazone was carried out adopting a single oral dose, randomized, complete two-way cross over design, with a wash out period of one week in twelve healthy human volunteers. The products were administered along with 200 ml of water after an over night fasting and blood samples (6 ml) were collected at 0.0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0, 16.0 and 24.0 h post dosing and were centrifuged at 3000 rpm and the plasma collected was stored frozen until analysis. The plasma drug concentration at different time intervals were estimated by a validated reversed phase HPLC method using C_{18} column. Pharmacokinetic parameters such as area under the plasma concentration-time curve, Time to Peak, Peak Plasma concentration, Elimination half life and Elimination rate constant were calculated and subjected to analysis of variance (ANOVA). On oral administration of the Reference product and the Test product in the fasting state exhibited Measurable Metformin and Pioglitazone blood levels in all the volunteers from 0.5 hr onwards. Measurable Metformin blood levels were noticed in all subjects up to 24.00 h for both Reference and Test Products.Measurable Pioglitazone blood levels were noticed in seven subjects up to 12.00 h for Reference Product and in eight subjects up to 12.00 h for Test Products. Based on the Pharmacokinetic data namely, AUC_{0-24}, T_{max}, C_{max}, k_{el}, Half life and AUC_{0-Inf} of the reference and the test products and their statistical analysis, it may be concluded that the Test product containing 30 mg of Pioglitazone and 500 mg of Metformin, is Bioequivalent to that of Reference product.

G1 Degradation profile of betacarotene in Carrot and its marketed formulation by visible spectrophotometry

Sapna Shrikumar, A. Agnees Neena*, Beeba John, T.K. Ravi

Department of Pharmaceutical Analysis, College of Pharmacy, SRIPMS, Coimbatore-44.

α and β-carotene are predominant vitamin A precursors found in many fruits and vegetables. Cis–trans isomerization reactions, which may occur during food processing, reduce the bioavailability of the provitamins. Because of the lowered biological activity of the cis isomer, characterization of the isomeric forms in cooked and processed products would be desirable. The forced degradation studies were carried out using standardization protocols such as pH, temperature, light, and oxidation.

500g of carrot pulp was weighed and isolation of β-carotene was carried out by subjecting to column chromatography using silica gel. The eluent used were hexane, hexane-diethyl ether and methanol. b-carotene was also isolated from 500mg of the powdered tablet.

From the stock solution of Betacarotene, different concentrations of 25, 50, 100, 125, 150, 175 and 200 mg/ml were prepared using the selected solvent. It was found from the calibration curve of Betacarotene that the correlation coefficient was 0.9992. All spectral measurements were made on Jasco V-530 UV/Vis spectrophotometer. The λmax of carrot extract and formulation were found to be 445 nm. The linear regression was found to be 0.999. This confirms the suitability of the method

The effect of pH was studied using various buffers such as pH 1.2-potassium chloride buffer, pH 2-potassium chloride buffer, pH 3- acid phthalate buffer, pH 5-acetate buffer and pH 7-monobasic potassium phosphate buffer. The effect of temperature at 28°C, 45°C and 55°C for thirty days, the light exposure studies under fluorescent light and oxidation studies with and without oxidizing agent were also analyzed on the prepared carrot extract and the marketed formulation.

Studies carried out on the proposed method indicated that there was no significant changes in the λ max at pH 1, 2, 3, 4, 5 etc. Temperature studies revealed that at room temperature all the spectral patterns were similar, at elevated temperature of 45°C the extract and the formulation were stable for 10 days and 12 days respectively and at 55°C for 2 and 3 days respectively. Light exposure studies revealed that the carrot extract and the formulation were stable for only 8 and 9 days respectively.

The present work has been designed to provide useful information about stability aspects of betacarotene and to have a keen assessment of the degradation pathway of this phyto principle in raw material and formulation. Hence the above studies and degradation pattern can be utilized to monitor the degradation pattern of betacarotene in carrots and its marketed formulation.

G2 Development and statistical validation of spectrophotometric methods for the analysis of anti-anginal and anti-ischemic agent – Trimetazidine Dihydrocholoride

K.Sujatha, K.Chitra, G.Kiruthika*, S.Kiruthika, H.Santhosh, X.Fathima Grace and J.Vasantha

College of Pharmacy, Sri Ramachandra Medical College & Research Institute (DU), Porur, Chennai

Trimetazidine Dihydrochloride, Chemically 1 – (2, 3, 4 – trimethoxy benzyl) piperazine dihydrochloride is a unique anti anginal and antiischemic agent.

The present work describes two statistically validated simple, rapid and accurate spectrophotometeric methods for the analysis of trimetazidine dihydrochloride. The methods are based on the reduction of ferric ion to ferrous by the drug.

Method I is based on the formation of green coloured chromogen with ferric chloride and Potassium ferricyanide. It shows absorption maxima at 770 nm and linearity in the concentration range of 20 – 60 µg / ml.

Method II is based on the formation of Yellow coloured chromogen with ferric nitrate in the presence of nitric acid. It shows absorption maxima at 420nm and linearity in the concentration range of 50 – 100 µg / ml.

The optical characteristics and precision studies like sandell's sensitivities, extinction co efficient, percent RSD, correlation co efficient, confidence limits, percentage recovery are calculated and the result of the proposed method are found to be reproducible. The methods appear to be economical, simple, sensitive and accurate for the analysis of trimetazidine dihydrochloride in Pharmaceutical formulations.

G3 Development and validation of spectrophotometric method of analysis of ethamsylate.

K. Chitra, K. Sujatha, Iman R. Ahmed*, K. Shalini, B. Lakshmi Priya, J. Vasantha.

Sri Ramachandra College Of Pharmacy, SRMC & RI (DU), Chennai 600116.

Chemically Ethamsylate is diethylammonium-2,5-dihydroxy benzene sulphonate and is used as a haemostatic agent. It stops haemorrhage from small blood vessels by stabilizing the capillary wall. It is indicated for prevention and treatment of capillary haemorrhage associated with haematemesis menorrrhagia and post-partum haemorrhage.

British pharmacopoeia prescribes titrimetry method for the assay of raw material. Dosage forms (tablet and injection) are not official in any pharmacopoeia. Literature survey did not reveal any method except a UV spectrophotometric method.

In the present investigation three simple and sensitive spectrophotometric methods have been developed and validated for the determination of Ethamsylate in tablet dosage form.

The developed methods are based on nitrosation of Ethamsylate followed by chelation of the o-nitroso derivative formed with Cu(ii) ions forming a stable purple coloured species (Method A), sodium molybdophosphotungstate in alkaline medium forming a blue coloured species (Method B) and by the reduction of ferric ions by the drug to ferrous, which inturn forms a complex with potassium ferricyanide and forms a blue coloured species (Method C) and exhibiting absorption maximum at 525nm, 745nm and 750nm respectively. Coloured chromogens formed (Method A, B and C) are stable for more than 4 hours and obeyed Beer's law in the concentration range of 2-20mg/ml. The results of analysis for the three methods have been validated statistically and by recovery studies. The proposed methods are simple, sensitive, selective and economical for the quantitative derermination of Ethamsylate in bulk drug and pharmaceutical formulations (tablets). The results are compared with those obtained using UV spectrophotometric method in water at 301nm.

G_4 Spectrofluorimetric determination of degradation pattern of betacarotene in carrot and its marketed formulation

Sapna Shrikumar*, A. Suganthi, T.K. Ravi

Department of Pharmaceutical Analysis, College of Pharmacy, SRIPMS, Coimbatore-44.

Shelf life of any medicine can be defined as the time period or duration up to which it is expected to retain its active ingredients i.e. 90% of the label claim when stored at recommended conditions.

From literature review, it is known that no spectrofluorimetric method for determining the pattern of degradation pathway of Betacarotene from natural source carrots and its marketed formulation have been developed.

Cis–trans isomerization reactions, which may occur during food processing, reduce the bioavailability of the provitamins. Because of the lower biological activity of the cis isomer, characterization of the isomeric forms in cooked and processed products would be desirable. The forced degradation studies were carried out using standardization protocols such as pH, temperature, light, and oxidation.

Fluorescence spectrofluorimeter with single quartz cell of 1cm path length (Hitachi, F-200), Sonicator (Frontline FS-4) and constant temperature water bath (Labtronic) were also used in the study.

The excitation and emission wavelengths were fixed at 347nm and 515nm respectively. The calibration curve was prepared and found to be linear.

The data analysis of the proposed study for pH showed no significant changes in λ max at various pH of 1, 2, 3, 5, 7, 10 M HCl and 0.1 M Na_2PO_4. At room temperature (28°C) all the spectral patterns were essentially similar and the percentage reduction of all trans betacarotene in the carrot extract and formulation after a period of 30 days were 20.17% and 17.35% resply. At 45°C the carrot extract and formulation for 6 days and 9 days respectively and the percentage reduction of all trans betacarotene were 49.52% and 53.75% resply. At 55°C the carrot extract and formulation were stable for 3 days and 4 days and the percentage reduction of all trans betacarotene were 73.25% and 70.87% respectively. At 45°C and 55°C, formation of a 'cis' peak was observed at 387nm. Under light exposure, the carrot extract and formulation were stable only for 3 and 4 days and the percentage reduction of all trans betacarotene was 69.43% and 64.81% respectively. Complete degradation of all trans Betacarotene occurred by the addition of an oxidizing agent and the percentage reduction was found to be 72.93% and 80.77% for the carrot extract and formulation respectively.

The present work has been designed to provide useful information about stability aspects of betacarotene and to have a keen assessment of the degradation pathway of this phyto principle in raw material and formulation. The forced degradation studies were carried out using standardized protocols and the degradation products were analyzed by developed spectrofluorimetric method.

G_5 Simultaneous estimation of Losartan potassium and hydrochlorthiazide in pharmaceutical dosage forms by RP HPLC

Ragin Shah*, B. N. Suhagia

B.M. Shah College of Pharmacy, Modasa, Gujarat

A simple, specific, accurate and precise reverse phase high performance liquid chromatographic method was developed for the simultaneous determination of losartan potassium (LP) and

hydrochlorthiazide (HCTZ) in its tablet dosage forms. A Lichrospherâ 100 C-18, 5 mm column having 20 x 4.6 mm i.d. in isocratic mode, with mobile phase containing 20 mM KH_2PO_4 buffer (pH adjusted to 3.00 ± 0.1 with 10 % v/v phosphoric acid): acetonitrile: tetrahydrofuran in 60:30:10 were used. The flow rate was 1.0 ml/min and effluent was monitored at 215 nm. The retention time of losartan potassium and hydrochlorthiazide were 3.26 min and 7.94 min respectively. Linearity for losartan potassium and hydrochlorthiazide were in the range of 4-40 mg/ml and 1-10 mg/ml with co-efficient of correlation (r) 0.9999 and 0.9998 respectively. Percentage recoveries obtained for both the drugs were 99.96 % and 99.93 % respectively. In replicate analysis n = 5 of two drugs in combination dosage forms by proposed method, the average content of losartan potassium and hydrochlorthiazide found were 50.04 mg/tab (RSD = 0.451 %) and 12.45 mg/tab (RSD = 0.809 %) respectively. Limit of detection (LOD) and Limit of quantification (LOQ) were found to be 0.08 mg/ml, 2 mg/ml and 0.1 mg/ml, 1 mg/ml of losartan potassium and hydrochlorthiazide respectively. The proposed method is accurate, precise, specific and rapid for simultaneous estimation of losartan potassium and hydrochlorthiazide.

G_6 Reversed phase HPLC method for estimation of Celecoxib in pharmaceutical dosage forms

Paresh B. Shah*, B.G. Chaudhari, B.K. Patel, R.R. Shah, D.M. Patel, K. Pundarikakshudu

B.M.Shah college of Pharmacy, College campus, Modasa, Dist. Sabarkantha, Gujrat 383 315

Celecoxib (CXB) is a new NSAID, which is a specific COX-2 Inhibitor and chemically it is 4-[5-(4-methylphenyl)-3-(trifluromethyl)-1H-Pyrazol-1-y1] benzenesulfonamide. Celecoxib is used in the treatment of rheumatoid arthritis, osteoarthritis and for the management of the pain in these conditions. It has better G.I. tolerability than classical NSAIDS. An HPLC method was developed for the determination of celecoxib, in pharmaceutical formulations. Analysis was performed on reverse phase *lichrospherl* C_{18} (4 x 250 mm, 5µ) column in isocratic mode, with mobile phase methanol: water (80:20 ml) was used. The flow rate was 1 ml/min and detection was performed at 252 nm. The retention time was 4.15 min. The linearity range was found to be 1 to 150 µg/ml. The correlation coefficient was 0.9998. The method was statistically evaluated for accuracy and precision, Recovery study values of 99-101% and relative standard deviation of less than 1% for the assay suggest the method is accurate and precise.

G_7 A validated RP-HPLC method for the determination of Rosiglitazone in bulk drug sample and pharmaceutical formulations

A. Adinarayana*, K.E.V. Nagoji and M.E.B. Rao

Pharmaceutical Analysis and Quality Assurance Division Roland Institute of Pharmaceutical Sciences, Berhampur(Gm) 760 010, ORISSA.

Rosiglitazone is a member of thiazolidinedione class of antidiabetic agent. Thiazolidinediones (troglitazone, rosiglitazone and pioglitazone) are selective agonists for nuclear peroxisome proliferator-activated receptor –gamma (PPARg). A rapid and sensitive high-performance liquid chromatography method was developed for the estimation of rosiglitazone in bulk drug sample and pharmaceutical dosage formulations. Tinidazole was used as an internal standard (ISD). A HPLC system consisting of isocratic pump, reverse phase C-18 analytical column, UV-visible detector set at 230nm and an integrator was used. The mobile phase composed of acetonitrile and water in the ratio of 50:50 (v/v), was pumped at a flow rate of 0.8 ml/min. The drug and ISD were eluted at 2.41 and 4.91 min respectively. The peak area ratio of drug to ISD versus drug concentration relationship was linear (r=0.9995). The method was validated for its linearity, precision, accuracy, limit of detection and limit of quantitation. The calibration curve was linear in the range of 1 to 15 mg/ml. The intra and inter–day variation was found to be less than 1% showing high precision of the assay method. The mean recovery of the drug from the solutions containing 2.5, 5 and 10 mg/ml was 99.2-100.3% indicating high accuracy of the proposed HPLC method. The limit of detection and limit of quantitation by this method were found to be 0.169 mg/ml and 0.563 mg/ml respectively.

G_8 Quantitative validated estimation of Celecoxib in their formulations by HPTLC

S.N. Meyyanathan* and B. Suresh

J.S.S. College of Pharmacy, Rocklands, PB. NO : 20, Ootacamund – 643 001, (T.N.)

Celecoxib, a nonsteroidal antiinflammatory agent is used in the treatment of pain. Only HPLC methods are available for the estimation. The present work describes the application of high performance thin layer chromatographic estimation of Celecoxib from its formulations. The analysis was carried out using Silica gel 60F 254 thin layer chromatographic (TLC) plate. The mobile phase comprised chloroform : methanol in the volume ratio of 1:9. Tizanidine was used as an

internal standard. After development it was then scanned densitometrically under deuterium lamp at 289nm. The Rf values are 0.78 and 0.58 for Celecoxib and Tizanidine respectively. The linearity range of the drug Celecoxib was 0.2-1.0µg/µl. The value of co-efficient of variation was found to be 0.8%. Percentage assay of levofloxacin was 100.1% and percentage recovery was found to be 102.2%, which indicates that the method is precise and accurate. The developed method was suitably validated. The simplicity, accuracy, sensitivity and precision of the developed method makes it as choice for routine quality control analysis.

G_9 Volume of entrapment - a better parameter for optimization of liposomal formulations

Girish Bende, * Gopal Das and R. N. Saha

Pharmacy group FD III, BITS, Pilani, Rajasthan 333 031

Liposomes are lyotropic liquid crystal mainly composed of amphiphilic bilayer entrapping a central aqueous core. They are becoming popular among formulation scientists due to revelation of their potential use in protein and peptide drug delivery during last decade along with their various advantages like structural flexibility in size, composition and bilayer fluidity, where their ability to incorporate large variety of drugs including hydrophobic compounds gives cutting edge. Extent and the site of their binding depend on both electrostatic and hydrophobic interactions.

The volume of the aqueous space within the liposomes is one of the most important factor influencing drug entrapment. Moreover, this parameter gives key information in process development and optimization of such formulations. Liposomes provide several sites of interactions and binding for foreign molecule. Along with the molecular weight and solubility data, the volume of entrapment not only provides explanation for supramolecular siting of drug molecules but also gives brief idea about the size of vesicles.

In present investigation an attempt has been made to optimize loading volume by studying volume of entrapment. Here, Liposomal formulation of Fluorescein was prepared using phosphotidyl choline and cholesterol, where different loading volume was given with the same concentration, keeping all other processing parameters constant. The formulations were estimated for Fluorescein content by using validated analytical method.

The volume of entrapment was constant for different formulations and is a better parameter for process optimization as larger this volume of aqueous core, the greater the amount of polar drugs that can be encapsulated. Loading volume can be optimized on the basis of volume of entrapment which reasons in better efficiency of entrapment.

G_{10} Simultaneous estimation of related substance present in pharmaceutical solvents like glycerin, sorbitol and propylene glycol

S. Manohar*, J. Raveendran, PL. Ramani, G.K. Sivaraman

M/s. Apex Laboratories Limited

Many chemical process have the potential to produce toxic impurities by the way of related substance. Manufacturing process should be adequately controlled so that the impurities / related substances do not exceed such established specification. We have developed and validated a sensitive, specific and accurate gas chromatographic method with flame ionization detection for the related substance estimation of other glycols present in the solvents like glycerin, sorbitol and propylene glycol.

The method was developed and validated on HP 6890 gas chromatograph using HP-Wax capillary column (30m X 320 mm X 0.25mm nominal). High purity grade nitrogen was used as carrier gas at 0.5ml per minute flow rate. The injector was maintained at 250°C. Samples were prepared in absolute alcohol. 1ml of sample were injected on the column in split mode. Flame ionization detector was used for detection of the compounds at 260°C. Temperature gradient was used for elution of compounds. Retention time of propylene glycol is 9.2, Ethylene glycol is 9.9 and Diethylene glycol is 19.9.

The proposed method was validated over the range of 20 mcg/ml to 100 mcg/ml for all the compounds. The correlation co-efficient was greater than 0.99. The accuracy was greater than 99%. The precision of the method was determined by replicate injections. The method was found to be rugged by different analysts. The method was found to be robust with slight change in temperature. The method is successfully applied to different pharmaceutical raw materials like Glycerin, Sorbitol and Propylene glycol.

G_{11} Gas chromatographic method for the determination of methyl sulfonyl methane in tablet dosage form

J. Raveendran*, S. Manohar, PL. Ramani, G.K. Sivaraman

M/s. Apex Laboratories Limited

A simple, fast and precise gas chromatographic method developed for the determination of Methyl Sulfonyl Methane (MSM) in tablet dosage form.The proposed method is carried out using HP-5

Crosslinked 5% Phenyl Methyl Siloxane capillary column (30m X 320mm X 0.25mm nominal) with nitrogen as carrier gas, column under constant pressure with column flow rate 1ml/min. The following parameters are maintained in Agilent 6890 series Gas Chromatography. Heater (injection Port) temperature 150°C, Oven temperature initial 100°C, 10°C ramp upto 200°C, and the detector temperature 250°C.

Inject the sample under split mode, split ratio is 50:1. n-Decane is used as the internal standard. The retention time of MSM is 6.7minutes. The proposed method was validated for parameters such as specificity, accuracy, precision, linearity, LOD, LOQ, system suitability studies, intraday and interday variation studies. There is no interference from the excipients present in the tablet form. The plot ratio of area of MSM and internal standard Vs concentration of MSM is found to be linear in the range of 0.25 mcg – 1.25 mcg / ml with correlation co-efficient r = 0.997. To study the accuracy and reproducibility and precision of proposed method, recovery experiments were carried out and results were between 99.98 to 101.5%. The proposed method gives good resolution between MSM and internal standard within short time less than 7 minutes.

The method developed is found to be accurate, precise, simple and fast and can be used for routine analysis of MSM in Pharmaceutical preparation.

G_{12} A validated RP-HPLC method for estimation of water soluble vitamins by isocratic separation

P. Surendrakumar*, A. Eswaraselvam, PL. Ramani, G.K. Sivaraman

M/s. Apex Laboratories Limited

A simple precise and rapid RP-HPLC method was developed for the simultaneous estimation of water soluble vitamins in pharmaceutical formulations like Tablet, Syrup and Drops using ion pairing reagent with shorter analysis time (with in 20 minutes). The method was carried on a waters HPLC system, symmetry C18 (250X4.6mm) column using a mixture of water: methanol: glacial acetic acid: 1-sodium hexane sulfonate (700:300:10:1.5gm) as a mobile phase, mixture of water: acetonitrile: glacial acetic acid (900:90:10) as a diluent, the flow rate was 1ml/minute and UV detector at 280nm.

The method was validated as per USP and ICH guidelines, which include accuracy, precision, linearity, specificity, system suitability, ruggedness and robustness. Accuracy of the method was determined through recovery studies by adding known quantity of standard drug in the pre anlayzed test solution and it was found to be 99-101%. Precision of the method was determined by assay of drugs in formulation by replicate injections. Lineartiy of the drug was obtained in the range of 450-1050mcg/ml for Ascorbic acid, 10-60mcg/ml for Riboflavin sodium phosphate, 300-700mcg/ml for Niacinamide, 10-30mcg/ml for Pyridoxine Hydrochloride, 50-150mcg/ml for Riboflavin and 10-60mcg/ml for Thiamine Hydrochloride. Robustness was determined by altering the ratio and pH of the mobile phase. Ruggedness was determined by performing the same assay on different instrument by different analyst and on different days and it was found to be 98.5-102%. Percent RSD of the assay was found to be within the limit of 1.5%

Hence the proposed method is simple, precise, accurate, rugged, robust, significant and suitable for the simultaneous and routine determination of water soluble vitamins in pharmaceutical multi vitamin preparation.

G_{13} Photodegradation study of a new fluoroquinolone gatifloxacin

M. Gandhimathi*, T.K. Ravi, Manjula Devi, Jaseela Majeed and Dileep Francis.

Department of Pharmaceutical analysis, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore 641 044.

The photo degradation of gatifloxacin, ±1-cyclopropyl-6 fluoro 1,4-dihydro-8methoxy-7-(3-methyl-1-piperazinyl) 4-oxo-3quinoline carboxylic acid, a new fluoroquinolone, a broad spectrum antibiotic was studied in aqueous solution exposed to artificial day light (2300 Lux intensity). Effect of various conditions as pH, concentration and temperature on photodegradation was studied. Gatifloxacin concentration was determined at regular time intervals by reversed phase HPLC. Results showed that, in the pH condition tested gatifloxacin underwent rapid photo degradation above pH 4.5 apparently following first order kinetics. Rate constants were dependent on the initial concentration of gatifloxacin at pH 4.5, half-lives ranged from198.0 ± 0.12 to 365 ± 0.51 hr for pH 4.5-7.4 and 582.35 ± 0.15 to 471.42 ± 0.25 for concentrations of 1mg/ml to 6mg/ml and 407.64 ± 0.71 to 55.44 ± 0.32 for temperatures from 28°C to 72°C. Analysis by electron impact mass spectrometry showed that the carboxylic acid group of gatifloxacin molecule might be degradaded during the photo degradation process. In conclusion, gatifloxacin is a photo liable molecule that should be carefully protected from light when used.

G_{14} Calorimetric studies to determine the thermodynamic parameters of inclusion complex of salbutamol with cyclodextrins to enhance solubility and stability in solution

Renu Chadha, Anupam Saini, Namdev Kashid

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh 160 014, India.

Salbutamol is a selective β_2-adrenoceptor agonist which is used widely as a bronchodilator in treatment of asthma and chronic obstructive lung disease as well as in obstetrics for the prevention of premature labour. Unfortunately, the drug is poorly water soluble and exhibits poor bioavailability. Inclusion complexes of the drug with cyclodextrins have been prepared aimed to increase water solubility and stability. Calorimetric technique have been employed to evaluate the stability constant and enthalpy changes associated with complexation process by determining the heat of solution of drug in water (pH 7) and aqueous solution of β-cyclodextrin and its hydroxypropyl derivative. Measurement of the stability or equilibrium constants K or the dissociation constants K_d of the drug-cyclodextrin complexes are important since this is an index of changes in physicochemical properties of a compound upon inclusion Calorimetrically determined molar heat of solution of pure drug is found to be exothermic and independent of concentration in solution (at pH 7). However, the system becomes more exothermic in presence of cyclodextrins and is found to be dependent upon the concentration of drug as well as cyclodextrin. Binding constants as calculated form calorimetric data is 473.75 $gmol^{-1}$ for

β-cyclodextrin complex and 636.55 $gmol^{-1}$ for hydroxy propyl derivative complex. Other thermodynamic parameters such as ΔH^0, ΔG^0 and ΔS^0 for complexation reaction with β-cyclodextrin have been found to be -2.32 $kJmol^{-1}$, -5.885 $kJmol^{-1}$, 43.72 $JK^{-1}mol^{-1}$ and its derivative to be, -3.54 $kJmol^{-1}$,-16.64 $kJmol^{-1}$ and 42.23 $JK^{-1}mol^{-1}$ respectively. The complexes were also been characterized by ^{1}H-NMR

G_{15} High performance thin layer chromatographic method for estimation of gatifloxacin in pharmaceutical dosage form

[1]S. A. Shah, [1]I. S. Rathod, [1]B. N. Suhagia and [2]Meeta Baldaniya*

1. Dept. of Quality Assurance, L. M. College of Pharmacy, Navrangpura, Ahmedabad 380009.
2. Dept of Pharmaceutical Chemistry, Shri Sarvajanik Pharmacy College, Mehsana- 384001

Gatifloxacin is recently developed third generation quinolones which inhibit DNA synthesis in susceptible bacteria. They are active in vitro against a many gram-positive and gram-negative bacteria.

A simple and sensitive, HPTLC method has been developed for the quantitative estimation of gatifloxacin in its pharmaceutical dosage form.

In HPTLC method, gatifloxacin was chromatographed on silica Gel 60 F_{254} TLC plate using n-Butanol:methanol:ammonia (6M) (5:1:2 v/v) as mobile phase. The gatifloxacin showed Rf value 0.47 ± 0.03 and scanned at 292 nm using CAMAG TLC Scanner 3. The method was validated in terms of linearity (400 – 1200 ng/spot), precision (intra-day variation 1.3 to 3.2%, inter-day variation 3.9 to 5.0%), accuracy (93.3 to 99.4%) and specificity. The limit of detection and limit of quantification for gatifloxacin were found to be 10 ng/spot and 50 ng/spot, respectively.

The method is simple, sensitive and precise; it is used for the routine quality control testing of marketed formulations.

G_{16} Extractive spectrophotometric determination of gatifloxacin

Neelaveni Thangavel, *Y.Haribabu, K.P.Beena, S.Angalaparameswari, P.Babu, S.Maheswari.

R.V.S.College of Pharmaceutical Sciences, Sulur, Coimbatore.

A sensitive spectrophotometric method in the visible region has been developed for the estimation of Gatifloxacin in the pure form and from its tablet formulation. The method is based on the formation of Mannich base of Gatifloxacin with Metanitro aniline and Paraformaldehyde in acidic medium. The yellow colored Mannich base formed was extracted with chloroform under experimental conditions. The color produced was found to be stable for 1hr and has maximum absorption at 453nm.The method obeys Beer's law within the concentration range of 10-40mcg/ml. Molar absorptivity and Sandell's sensitivity were found to be $6.678x10^{-3}$ mole/lit/cm, and $25x10^{-3}$mcg/cm^2/0.001AU respectively. The method was validated statistically. Recovery studies gave satisfactory results indicating that none of the common additives and excipients interferes the assay method.

The proposed method was found to be accurate, reproducible, and consistent and was successfully applied for the analysis of marketed tablets and can be used for the routine analysis of formulations.

G17 Estimation of pioglitazone and metformin by derivative spectrophotometry and RP-HPLC in tablets

M.B. Shankar, V.D. Modi*, D.A. Shah, B.J. Patel and M. Geetha

A. R. College of Pharmacy, V. V. Nagar, 388 120

Two precise, accurate and specific methods were developed for estimation of pioglitazone and metformin. In derivative spectrophotometry (Method 1), mixture of methanol and acetonitrile (30:70) was used as solvent. The overlain second derivative spectra revealed two wavelengths that could be used for analysis of these two drugs. For estimation of pioglitazone 227.55nm (zero crossing point of metformin) and for metformin 257.25nm (zero crossing point of pioglitazone) were used as analytical wavelengths. Calibration curves were plotted from the second derivative spectra at 227.55nm for pioglitazone in the concentration range of 8 – 40 mg/ml (r = 0.9984) and at 257.25nm for metformin in the concentration range of 4 - 12 mg/ml (r = 0.9986).

For method 2, (HPLC) mixture of acetonitrile, water and acetic acid (750:250:3, pH adjusted to 5.5 with ammonia water) was used as mobile phase at a flow rate of 0.5 ml per minute on 5 mm ODS C_{18} column. Detection was made at 230 nm. Both the drugs were well resolved over the stationary phase and the retention time was 8.51for pioglitazone minutes and 15.99 minutes for metformin. Calibration curves were plotted using peak area verses concentration for both the drugs in the concentration range of 4 – 20 mg /ml. (r = 0.9933 for pioglitazone and 0.9958 for metformin)

The results of analysis for these two methods have been validated statistically and by recovery studies. Both the methods were found to be accurate and the percentage recovery was more than 99% for pioglitazone and metformin.

G18 Quantitative estimation of clobetasol propionate, betamethasone dipropionate and clobetasone butyrate by RP-HPLC using same mobile phase in topical preparations

P. Surendrakumar*, J. Raveendran, PL. Ramani, G.K. Sivaraman

M/s. Apex Laboratories Limited

A RP-HPLC method has been developed and validated for the determination of three steroids ; Clobetasol propionate, Betamethasone Dipropionate and Clobetasone butyrate in ointment / creams dosage forms. All the above three drugs are being used in the treatment of dermatitis. Literature survey reveals that a number of spectrophotometer and HPLC methods for individual determination of Clobetasol propionate, Betamethasone Dipropionate and Clobetasone butyrate are available. But no method is reported for determination of these three drugs, using the same mobile phase, same column and same condition. The dilution of standard and sample were made in mobile phase. The separation were achieved by using C_8 (15cmx4.6mm) column, in isocratic mode with mobile phase, mixture of Acetonitrile:Tetrahydrofuran:1% Acetic acid (25:20:55), the flow rate was 1.5 ml/minute and UV detector at 254 nm. The retention time of Clobetasol propionate, Betamethasone Dipropionate and Clobetasone butyrate was 12.8, 12.3 and 19.1. Linearity obeys the beers law in the concentration range of 20mcg-60mcg for above three drugs. The HPLC method was validated with respect to parameters such as specificity, accuracy, precision, Linearity and range, LOD and LOQ. System suitablility was studied as per ICH/USP guidelines.

Recovery study was also carried out by adding known quantity of standard drug in the pre anlayzed test solution and calculated the percentage recovery. The percentage recovery study for all three steroids was found to be 99-101%. The proposed method was found to be accurate, precise, simple and rapid and can be used for routine analysis in topical preparation.

G19 Method development and its validation of vitamin a acetate, vitamin D3 and vitamin E acetate by HPLC

S. Manohar*, A. Eswaraselvam, PL. Ramani, G.K. Sivaraman

M/s. Apex Laboratories Limited

The proposed method has the advantage of simultaneous determination of Vitamin A Acetate, Vitamin D3 and Vitamin E Acetate in tablet dosage form with simple solvent system. Using Acetonitrile, Methanol and n-Hexane (4.5:4.5:1) as a mobile phase with Tetrahydrofuran, Acetonitrile and Iso Propyl Alcohol (4:4:2) as a diluent. Retention Time (RT) of Vitamin A Acetate, Vitamin D3 and Vitamin E Acetate which are 1.5, 2.4 and 3.3 minutes respectively. This provides shorter analysis time (with in 5 minutes) and conserves the mobile phase solvent system.

The method was validated based on USP and ICH parameters which include accuracy, precision, linearity, specificity, system suitability, ruggedness and robustness. Accuracy of the method was determined through recovery studies by adding known quantity of standard drug in the pre anlayzed test solution and it was found to be 99-100.5%. Precision of the method was determined by assays of drug formulation by replicate injections. Linearity of the drug was obtained

in the range of 10-50mcg/ml for Vitamin A Acetate, 20-60mcg/ml for Vitamin E Acetate and 1-5mcg/ml for Vitamin D3 . Robustness was determined by carrying out assay during which the mobile phase ratio and pH of the mobile phase was altered. Percent recovery was found to be within 99-102%, which indicates the lack of influence on test results by operational and environmental variables for the proposed method. Ruggedness was determined by performing the same assay on different instrument by different analyst and on different days and it was found to be 98.5-102%. Percent RSD of the assay was found to be within the limit of 1%.

Hence the proposed method is simple, precise and suitable for the simultaneous and routine determination of Vitamin A, Vitamin D3 and Vitamin E.

G_{20} Reverse phase high performance liquid chromatographic determination of tizanidine and rofecoxib in tablets

Gandhimathi. M, Ravi T. K, Susheel John Varghese*

Department of Pharmaceutical Analysis, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

A reverse phase high performance liquid chromatographic method to determine tizanidine and rofecoxib in combination was developed and applied to the pharmaceuticals. The separation was carried out on a waters, sperisorb ODS column (4.6 ´ 150 mm, 0.5 m particle size). The mobile phase consisted of 1% v/v triethylamine (pH adjusted to 2.5 using dilute orthophosphoric acid) : acetonitrile in the ratio 55 : 45 % v/v. This method allows the determination of 0.1 to 0.5 mg/ml of tizanidine and 1.2 to 6.0 mg/ml of rofecoxib, alongwith 10 mg/ml of nimesulide(internal standard). Detection wavelength of 303 nm and flow rate of 0.8 ml/min were fixed for the study. The limit of detections (LOD) for tizanidine and rofecoxib were found to be 10 ng and 1 ng respectively. The limit of quantification (LOQ) for tizanidine and rofecoxib were found to be 80 ng and 12 ng respectively. The amount of drug present in the tablet and the recovery studies were also carried out. The %RSD of recovery studies for tizanidine and rofecoxib were found to be 0.0673 and 0.0146 respectively. Validation of the method was done for its accuracy, precision, ruggedness and robustness. System suitability parameters were also calculated.

G_{21} Simultaneous spectrophotometric estimation of etofylline and theophylline in tablet dosage from.

Mehre A.P., Tawade S.D.*, Hedau P.B.

Nagpur college of Pharmacy, Wanadongri, Hingna Road, Nagpur 441 110

This paper presents simple, economical and accurate spectrophotometric method for simultaneous quantitative estimation of Etofylline and Theophylline in tablet dosage form.

In 0.1N HCl, Etofylline and Theophylline shows I max 274nm and isobestic point 237nm. Simultaneous estimation of both the drugs is carried out by absorbance ratio method.

Quantitative determination of both the drugs is carried out within Beer"s concentration range and validation of the proposed method is carried out by recovery and ruggedness study.

G_{22} Visible spectrophotometric estimation of gatifloxacin and moxifloxacin in pharmaceutical dosage forms

S.A.Patel*, C.N.Patel, M.M.Patel, P.U.Patel, M.B.Patel

* Dept. of Pharmaceutical Chemistry, Shree S.K. Patel College of Pharmaceutical Education & Research, Ganpatvidyanagar, Mehsana, Gujarat, India - 382711

A simple, sensitive, accurate and rapid spectrophotometric method for the estimation of Gatifloxacin and Moxifloxacin using Folin-ciocalteau (F.C) reagent in presence of 20% sodium carbonate is described. The blue colour chromogen formed is measured at wavelength of maximum absorption 760 nm and 755 nm for Gatifloxacin and Moxifloxacin respectively against reagent blank. The chromogen formed was stable for at least 3 hrs. and obeyed linearity over 5.0 to 50 mcg/ml for gatifloxacin and 5.0 to 40 mcg/ml for moxifloxacin.

Gatifloxacin (GTF) and Moxifloxacin (MXF) are a new broad spectrum fluorinated quinolones antibacterial agent. Chemically gatifloxacin is 1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(3-methyl-1-piperazinyl)-4-oxo-3-quinolinecarboxilic acid.[1] GTF and MXF are not official in any pharmacopoeia; hence there is no official method for the estimation of GTF and MXF in pharmaceutical formulations. Only HPLC[2] and LC/ESI-MS/MS[3] methods are reported for the estimation of GTF in the human plasma. Chemically moxifloxacin is 1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4aS,7aS)-octahydro-6H-pyrrolo(3,4-b)

pyridin-6yl]-4-oxo-3-quinolinecarboxilic acid. Only HPLC, LC/MS, Capillary electrophoresis and spectrofluorimetric methods are reported for the estimation of MXF in the pure form, tablet and biological fluids.

The recovery experiments were performed by adding known amount of drug to the preanalyzed formulation and reanalyzing the mixture by proposed method. The results were validated statistically and the % recovery was found in the range of 99.1 to 100.4. The proposed method is new, simple, sensitive, accurate, precise and can be successfully employed in the routine analysis of these drugs in pharmaceutical dosage forms.

G_{23} Assay of valsartan and hydrochlorothiazide from dosage form by RP- HPLC

K. M. Patil*, K. K. Nerurkar, N. R. Lad, I. Bhoir and A. M. Bhagwat

Valsartan, Hydrochlorothiazide, HPLC

The present paper explains an isocratic RP- HPLC method for the separation and estimation of Valsartan (N-pentanoryl- N-[2'-(1H-tdrazol- 5- yl) biphenyl- 4- yl- methyl]- L- valine) and hydrochlorothiazide (6-chloro-3, 4-dihydro-2H-1,2,4-benzothiadiazine-sulfonamide1,1-dioxide) in bulk as well as in dosage form using losartan- K as internal standard. A combination of these drugs (valsartan 80 mg and hydrochlorothiazide 12.5 mg) is used in the management of hypertension. The stock solutions of these two drugs were prepared in mobile phase and a 20 mL aliquot of these solutions were injected on Zorbax phenyl (250 X 4.6 mm, 5 mm) column. The drugs were eluted by using water: acetonitrile 40: 60 (v/v) containing 0.1 % triethylamine, the pH of the mobile phase was adjusted to 3.50 with 20 % phosphoric acid. The separated drugs were detected on UV detector at the wavelength 210 nm. The peaks were examined for chromatographic figures of merit. Peak areas were taken as the function of detector response. The linear dynamic ranges for valsartan and hydrochlorothiazide were 64- 96 ug/ml and 10- 15 ug/ml. The analytical performance parameters like accuracy, precision etc were determined in order to validate the method. After validation the method was applied to the assay of the two drugs available in the market. Application of the method reveals that content of valsartan was 80.07 hydrochlorothiazide 12.5 mg against the labeled dose of 80 mg of valsartan and 12.5 mg of hydrochlorothiazide.

G_{24} Simultaneous estimation of trace impurities from carvedilol by packed column supercritical fluid chromatography

Nilesh R. Lad*, K.M. Patil, K.K. Nerurkar and I.C. Bhoir

Shri C B Patel research centre for chemistry & biological sciences, IIIrd floor, Bhaidas Hall Building, Vile Parle (W), Mumbai 400 056

A reproducible and efficient method for the simultaneous determination of Carvedilol and its impurities viz., Impurity A, Impurity B, and Impurity C has been developed using packed column supercritical fluid chromatography. The separation was done using Nucleosil C_{18} (250 x 4.6 mm) 5µm column The mobile phase was supercritical fluid CO_2 modified with 0.5 % methylamine in methanol as the modifier which has following programming regime:-

Time	% of Modifier Flow Rate
0.0 – 3.0 min	5
3.0 – 5.0 min	40
5.0 – 11.0 min	25
11.0 – 19.0 min	100
19.0 – 22.0 min	5

The densities and polarities of the mobile phase were optimized form the effect of pressure and temperature on the retention time. The analytes were detected at 230 nm. Chromatographic figures of merit, calibration data and accuracy and precision were determined to assess the viability of the method. The method has been successfully used to analyse for the estimation of impurities in Carvedilol raw material.

G_{25} Simultaneous estimation of atenolol and nifedipine in combined dose tablet

M.K. Ramteke*, A.V. Kasture

Nagpur college of Pharmacy, Wanadongri, Hingna road, Nagpur-441110

Fixed dose combination tablets containing Atenolol and Nifedipine are clinically used as antihypertensive, antianginal and coronary vasodilator.

Methods have been reported for their estimation in combined dose tablet. The present method describes, simple, accurate and precise HPTLC and Spectroscopic method for their simultaneous estimation.

In HPTLC method, methanolic standard and sample solutions were chromatographed on precoated silica gel 60 GF_{254} plates using

cyclohexane:methanol:ethylacetate:ammonia :: 5:1.5:3:0.5 as mobile phase followed by densitometric scanning at 230 nm. The R_f values of Atenolol and Nifedipine under standard condition were 0.08 and 0.65 respectively. Their respective concentration-response linear ranges were 1-20 mg and 1-20 mg. The mean recoveries from tablet matrix by standard addition method were 100.41% (± 0.014) and 100.60% (± 1.569). The spectrophotometric method has been based on the exploitation of multicomponent mode of Shimadzu double beam spectrophotometer, model 1601. Methanolic mixed standard and sample solutions were scanned over 210-315 nm range (sampling wavelengths 228, 259, 276, 291 and 312 nm). The drugs individually and in mixture obey Beer's law over concentration range 0-30 mg/mL and 0-25 mg/mL at all five sampling wavelengths. The mean recoveries from tablet by standard addition method were 99.88 (± 2.314)% and 99.824 (± 2.348)%.Both the methods are suitable for simultaneous estimation of Atenolol and Nifedipine tablet.G 26

G_{26} "Quantitative estimation of the gallic acid and glycyrrhizin from polyherbal eye drop by HPTLC".

Ashutosh Pathak*, Pradeep Mandurkar, Shilpa Shukla, K.P. Bhusari, B.K. Shrikhande

Baidhyanath research foundation ltd., 20, Great Nag Road, Nagpur – 440 009.

Conjunctivitis is most frequently occurring ocular disease. Many eye preparations having only antibiotic therapy & steroids are used but has it's own drawbacks. Hence to exploit the utility of medicinal plants, a polyherbal eye drop was formulated by using Ocimum sanctum, Boerhaavia diffusa, Glycyrrhiza glabra and Emblica officinalis. Our study was aimed to develop a HPTLC method for quantitative determination of active constituents Gallic acid and Glycyrrhizin. Though there are several methods for estimation of Glycyrrhizin and gallic acid in the crude drug, drug extract or formulations, but no method was available for estimating the same from polyherbal eye drop formulation. The analysis was carried out by using precoated silica gel $60F_{254}$ TLC plate. The mobile phase Toluene: Ethyl Acetate: Glacial Acetic acid(6.25 : 3.75 : 0.25) and Toluene: Ethyl acetate: Glacial Acetic acid: Formic acid(2.0 : 4.5 :2.0 :0.5) was found more suitable to resolve the test samples and to quantify 18B-Glycyrrhitinic acid and gallic acid respectively. The plate was scanned and quantified at 262nm and 295nm and the calibration curve was linear in the range of 0.2ug-2.6ug &0.8ug-4.0ug for the gallic acid and 18B-glycyrrhitinic acid respectively. The method used for quantitative estimation was tested for accuracy by recovery study. Limit of detection, limit of quantification, precision etc. were also used to validate the method.

G_{27} Simultaneous estimation of pantoprazole and domperidone in pharmaceutical preparations by using spectrophotometric method

Kakde R.B.*, Dhurvey Y. R., Gedam S. N., Meghal S.K., Kasture A. V.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur-440 033.

A simple, rapid and precise simultaneous equation method has been developed for the simultaneous estimation of Pantoprazole (PAN) and Domperidone (DOM) in pharmaceutical preparations. The marketed survey revealed that the combination is recently introduced in the market in the form of capsule formulations. No method has been reported for the estimation of PAN and DOM in combined dosage form.

The present study deals with the development of UV spectrophotometric method for estimation of PAN and DOM in capsule formulations. Shimadzu UV 2401 spectrophotometer was used. The $\ddot{e}_{max}$ of PAN and DOM was found to be 331 nm and 284 nm respectively. The calibration curve was linear in the range of 10 to 50 ìg /ml for PAN and 10-40 ìg/ml for DOM at their respective wavelength.

The method developed is suitable for the estimation of drugs in standard laboratory mixture as well as for marketed drugs and found to yield better results. The percentages recovery for PAN and DOM were close to 100% respectively. Hence the method can be used for routine analysis of PAN and DOM in capsule formulations.

G_{28} Method development and validation of gliclazide and metformin HCl from tablet using HPTLC

Zahid Zaheer, Deepali Mhaske*, Jitender Bariwal, S.S Kadam and S.R Dhaneshwar.

Department of Pharmaceutical Chemistry, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune 411 038.

Chemically Gliclazide is N- [(hexa hydro cyclopenta [c] pyrrol2 (1H)-yl) aminocarbonyl]-4-methyl benzene sulphonamide and Metformin HCl is 1,1-dimethyl biguanide and are antidiabetic. A combination of 80 mg of Gliclazide and 500 mg of Metformin HCl are commercially available in tablet form. Literature survey revealed that there are number of methods reported on the estimation of Gliclazide and Metformin individually or in combination with other drugs.

However, there is no method reported for the simultaneous estimation of these drugs.

The present work describes HPTLC method for the simultaneous estimation of these two drugs in tablets. The drugs were separated on RP- 18 HPTLC plates using mobile phase of Acetonitrile: Phosphate buffer (7.2 pH) 50:50 containing 0.2 g of 1-pentene – sulphonic acid solution as ion pairing reagent, with scanning at 235 nm.

The R_f values under standard conditions were 0.28 and 0.68 for Gliclazide and Metformin HCl respectively. The concentration response plot was linear over the range 56-104ng (Gliclazide) and 350-650ng (Metformin) with correlation coefficients well above 0.9989 and 0.9987.

The results of estimation under standardized conditions were precise. The percent recoveries of drugs from the ANOVA method were found to be in the range of 99.01% - 99.88% for Gliclazide and 99.66% - 100.3% for Metformin HCl. In conclusion the method developed is simple, fast, accurate and precise which can be used for routine analysis for these formulation.

G_{29} Cleaning validation of beta lactam group of antibiotics

N.P. Chotai, V.A.Patel*,K.H. Shah, U.A. Patel,B.G. Patel and H.V.Patel

A. R. College and G.H. Patel Institute of Pharmacy, Vallabh Vidyanagar - 388120 (Gujarat)

Multiple product facilities clearly represents a more difficult challenge. Procedurally steps must be taken in multiple product facility to ensure that cross contamination potentials are eliminated. Change over of product from one product to another product must be carefully controlled. Especially when common facilities are used for the production of various dosage forms of Beta Lactam group of antibiotics, care must be taken to ensure that cross contamination is prevented. Looking at the risk of potential hazards of cross contamination by penicillin to cephalosporin and vice versa, the present study was under taken with a view to assess the effectiveness of cleaning procedure being used in one of the WHO approved pharmaceutical plant in Gujarat having common facilities for manufacture of dosage forms of Beta Lactam group of antibiotics. A detailed cleaning validation programme was designed which included selection of dosage forms of Beta Lactam group ,selection of sampling points, cleaning method, development of analytical method for actives, sampling method, recovery studies and acceptance limit determination.

In present study good swabs recovery was obtained with respect to amoxycillin trihydrate (91.84%), cephalaxin (85.04%) and cefadroxyl (94.68%). The values of residue of actives on different sampling point were found within acceptance limit of 10mcg/sqcm recommended by USFDA guidelines and lilly criteria.It may be concluded that the cleaning procedure being used in Beta Lactam manufacturing plant was found satisfactory.

G_{30} Development of apectrophotometric methods for analysis of cefpodoxime proxetil in pharmaceutical dosage forms

M. M. Karande*, S. V. Thakkar and B. S. Kuchekar.

Government College of Pharmacy, Vidyanagar, Karad-415124, MS, India.

Cefpodoxime, a third generation cephalosporin, is administered orally as a proxetil ester which is hydrolysed on absorption to cefpodoxime. Chemically it is 1-[(isopropoxycarbonyl) oxy]ethylester of (Z)-7-[2-(2-amino-1,3-thiazol-4-yl)-2-methoxyaminoacetamido]-3-methoxymethyl-3-cephem-4-carboxylic acid.

Present work describes two simple, precise, validated and sensitive methods for the estimation of Cefpodoxime proxetil in pharmaceutical formulations. Method A estimates drug in its bulk and dosage form using ferric nitrate and 3-methyl-2-benzothiazolinone hydrazone hydrochloride (MBTH) reagent to give green colored complex measured at 637nm. Method B is based on the reduction of ferric ions in ferric nitrate to ferrous ions by the drug, which further in presence of potassium dichromate produces chromogen measured at 620 nm.

The proposed methods determine Cefpodoxime proxetil in concentration range of 20 – 100 mg / ml (r=0.9938) for Method A and 15 – 35 mg / ml (r =0.9963) for Method B. The molar absorptivity and sandal's sensitivity values indicated good sensitivity of the methods. The regression equation for cefpodoxime proxetil was found to be y = 0.0062 x + 0.1704 for Method A and y = 0.0498 x + 0.3088 for Method B. The % RSD values were calculated as 0.43 for Method A and 0.46 for Method B. The stability of chromogen was established for 1.15 h and 2 h for Method A and Method B respectively. The methods were statistically evaluated for accuracy and precision. Recovery study was performed and percent recovery values indicated non-interference from formulation excipients. The methods in present investigation can be successfully applied to the determination of Cefpodoxime proxetil in pure form and pharmaceutical dosage forms with good accuracy and precision.

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DPC GOC 08137 P03

G_{31} Spectrophotometric method for the assay of Non-cardio selective b blocker – carvedilol in pharmaceutical dosage forms

K.Sujatha, K.Chitra, X. Fathima Grace*, H. Santhosh, G.Kiruthika, S.Kiruthika and J.Vasantha

College of Pharmacy, Sri Ramachandra Medical College and Research Institute (DU), Porur, Chennai – 600116.

Carvedilol, chemically 1– carbazol – 4 – yloxy – 3 -[2–[2–methoxy phenoxy) ethyl amino] propan-2-ol is a non-cardio selective b blocker. It is official in Martindale, The Complete Drug Reference.

The present work describes three statistically validated simple, rapid, sensitive and accurate spectrophotometric methods for the estimation of carvedilol in pharmaceutical dosage forms.

Method I is based on the redox reaction between the drug and Folin-ciocalteu reagent to form a blue coloured chromogen having absorption maxima at 745 nm and linearity in the concentration range of 2-10 mcg/ml (r=0.9994) with a relative standard deviation of 0.0045.

Method II is based on the formation of stable green coloured chromogen with ferric chloride and potassium ferricyanide exhibiting maximum absorption at 770 nm and linearity in the concentration range of 0.5 – 4.0 mcg/ml(r=0.9986) with a relative standard deviation of 0.006.

Method III is based on the UV spectroscopy of the drug. Carvedilol is dissolved in methanol and absorbance is measured at 245 nm. It shows linearity in the concentration range of 4-10 mcg/ml (r=0.999) with a relative standard deviation of 0.0093.

The effects of various parameters such as reaction time, volume of reagent and stability of the coloured species formed are studied. Results obtained by the proposed methods are found to be reproducible. The methods are simple, accurate and precise and can be employed for the quantitative estimation of Carvedilol.

G_{32} A New HPTLC method for separation and quantification of amino acids

S. A. Shah[1], I. S. Rathod[1], Dharitri Kanakia* [2]

1. Dept. of Quality Assurance, L. M. College of Pharmacy, Ahmedabad.
2. Dept. of Chemistry, Shri Sarvajanik Pharmacy College, Mehsana.

Amino acids are the structural units of proteins. They are building blocks of human body and have a great nutritional value.

A sensitive and simple HPTLC method was developed for separation and estimation of amino acids using prederivatization technique. The amino acids (glycine and isoleucine) were derivatized with dichlone in dimethyl sulfoxide. The derivatized amino acids were extracted with chloroform. The chloroform extract was spotted on silica gel 60 F_{254} TLC plate. The plate was developed using a mixture of

Benzene: Methanol: Ethyl acetate (60:30:10 v/v) as the mobile phase. It was observed that glycine (R_f - 0.3 ± 0.03) and isoleucine (R_f - 0.6 ± 0.03) were well resolved. The densitometric evaluation of derivatized amino acids was performed at 470 nm.

The proposed High Performance Thin Layer Chromatographic method was validated for linearity (50 - 100 ng/spot for glycine and isoleucine), precision(% CV - intraday precision - glycine - 2.41 - 4.26% and isoleucine - 2.81 - 4.95% and interday precision - glycine - 4.66 - 7.98% and isoleucine - 4.64 - 7.16%), accuracy (glycine - 98.84 -104.4% and isoleucine - 100.35 - 106.05%) and specificity (peak purity – correlation for glycine – 0.9999 and for isoleucine – 0.9997).

This method can be used for separation and quantification of amino acids in formulations and other matrices.

G_{33} Spectrophotometric estimation of levofloxacin in health care medicines

K.Chitra, K.Sujatha. N.Girija[1], Amitabha Ghosh*, Sanjiv Kumar, Kamakshi Kaushik V.V, Rajiv Ranjan & J.Vasantha

Sri Ramachandra College of Pharmacy, SRMC & RI (DU), Chennai –600 116

1. Mother Terasa College of Pharmaceutical Sciences

Levofloxacin is 9 – fluoro – 2,3 dihydro – 3-methyl–10 (4 – methyl – 1- piperazinyl) –7- oxo-pyrido (1,2,3 –de) – 1,4 – benzoxazine – 6 carboxylic acid. The more active levo isomer of ofloxacin (a racemic mixture of D, L isomers) that has improved pneumoniae including strains resistant to penicillins, Enterococcus and *Staph aureus*, compared to ciprofloxacin.

Literature survey reveals HPLC, potentiometric and polarographic methods for the determination of drug in pharmaceutical dosage forms.

The present work describes four statistically validated simple rapid, sensitive an accurate UV spectrophotometric and colorimetric methods for the estimation of levofloxacin using 0.01N NaoH, (Method

A) water (Method B), Folin ciocaltu reagent (Method C) and potassium ferricyanide (Method D) in pharmaceutical dosage forms.

Levofloxacin was determined in pure and in dosage form using absorption maximum at 205 nm in 0.01NaOH (Method A) and 210 nm in water (Method B) with the linearity of 20-50 mcg/ml and 60 – 80 mcg / ml. range.

The third method (Method C) was based on the reduction of ferric ions to ferrous ion by the drug. The ferrous ions reacted with potassium ferricyanide producing blue coloured chromogen was measured at 745 nm with the linearity range of 5-10 mcg / ml.

The fourth method (Method D) was based on the formation of a blue chromogen on treatment with Folin ciocalteu reagent in the presence of 1N NaOH which showed the maximum absorption at 745 nm, with the beer's law range of 5-18 mcg/ml.

Sandells sensitivity, extincition coefficient, % relative standard deviation, correlation coefficient, confidence limit were determined. Recovery studies were found to be 98.51+ 0.185 in 0.01N NaOH, 101.4+1.71 in H_2O, 99.25 + 0.2859 (Method C) and 99.82 + 0.5 (Method D). The proposed methods appear to be economical simple sensitive, reproducible and accurate for bulk as well as pharmaceutical dosage forms.

G_{34} Spectrophotometric determination of lercanidipine

Arvind.B.Karadi*[1], Hariprasanna. R.C.[1] S.Appala Raju[2] and Arun Kumar Beknal[2]

RMES College of Pharmacy, Gulbarga (Karnataka)[1], HKE's College of Pharmacy, Gulbarga (Karnataka) [2]

Lercanidipine (1), (±)-2-[(3,3-Diphenylpropyl) methylamino]-1,1-dimethyl ethylmethyl-1,4-dihydrodimethyl-4-(m-nitrophenyl)-3,5-pyridine dicarboxylate hydrochloride is a vasoselective dihydropyridine calcium antagonist which causes systemic vasodilation by blocking the influx of calcium ions through L-type calcium channels in cell membranes. It is more lipophilic with longer duration of action than most other drugs in its class including amlodipine, nitrendipine, isradipine and nimodipine. Literature survey reveals that there is no analytical report for the quantitative estimation of Lercanidipine in bulk drug and its pharmaceutical formulations.

In the present investigation, authors have developed three simple, sensitive and accurate spectrophotometric methods for the quantitative estimation of Lercanidipine. The method A is based on UV absorption of drug in methanol exhibiting absorption maximum at 233nm and obeyed Beer's law in the concentration range of 2-10mg/ml. Methods B and C are by visible spectrophotometry after converting it into its reduced form in situ by zinc granules and hydrochloric acid in methanol at room temperature. The complete conversion of Lercanidipine to its reduced form (2) in situ has been confirmed by the disappearance of a peak at 233nm in its UV spectrum which is a characteristic peak in the UV spectrum of Lercanidipine itself in methanol. The presence of aromatic amino group in reduced Lercanidipine enabled the use of its condensation reaction with p-dimethylamino cinnamaldehyde (PDACA) in Method B to form a pink coloured chromogen (3) with an absorption maximum at 529.2nm and obeyed Beer's law in the concentration range of 2-10mg/ml. In method C, the reduced Lercanidipine was diazotised with nitrous acid ($NaNO_2$/ HCl) at 5°C and the diazonium salt (4) thus formed is coupled with Bratton-Marshall reagent [N-(1-naphthyl) ethelene diamine dihydrochloride]. The purple coloured chromogen (5) formed exhibited absorption maximum at 554nm and obeyed Beer's law in the concentration range of 2-10mg/ml. In both methods, colours are stable for more than 4 hr. Spectrophotometric parameters were established for standardisation of the methods including statistical analysis of data.

G_{35} Reverse phase HPLC determination of nateglinide in pharmaceutical formulations

Dr A. Rajasekaran and S. Murugesan

Arulmigu Kalasalingam College of Pharmacy, Krishnankoil

Nateglinide is a derivative of the amino acid, D-phenylalanine. It is a novel oral hypoglycemic agent used for the management of type-II diabetes. A new and simple RP-HPLC method has been developed for the determination of Nateglinide for bulk drug and its tablet dosage form. The method involves the use of Hypersil ODS (10 P) C18 column 30 cm x 4.6 mm (i.d). Acetonitrile: Sodium ortho dihydrogen phosphate in the volume of 30:70, adjusted to pH 6 with ortho phosphoric acid was used as mobile phase. The flow rate was 1 ml/ minute and the effluent was measured at 210 nm. Roxithromycin was used as internal standard. The method was found to be linear in the range of 5 -20 P g/ ml and the correlation coefficient war r = 0.9984. The proposed method was applied successfully to quantitate the amount of Nateglinide in tablet dosage form.

G36 Development and validation of photostability indicating HPLC method for danazol

Jadhav G.S., Pedgaokar Y.* and Vavia P.R.

Pharmaceutical Division, University Institute of Chemical Technology, Matunga, Mumbai - 400 019

This work describes development and validation of a simple, accurate, sensitive and selective stability indicating reverse phase HPLC procedure for Danazol. The photolysis was carried out in glass vials under UV light at 254 nm. The separation between drug and its photo degradation products was carried out using HiQ Sil C18 ODS column (4.0 mm x 250 mm). The drug was eluted using mobile phase, Acetonitirle: Water in the ratio 65:35 at a flow rate of 1.0 ml/min. The detection was carried out at 286 nm.

The proposal chromatographic method gave good resolution of the drug from its photo degraded products. The linearity of the method was established in the concentration range of 0.20-20 µg/ml with a correlation coefficient of 0.9999. Chromatographic limit of detection (LOD), limit of quantification (LOQ), accuracy, precision, ruggedness and recovery have also been determined to validate this method. The limit of detection of Danazol was 6 ng/ml and limit of quantification was 25 ng/ml. Good reproducibility and precision reflected by low% RSD values (below 2%) for the within-day data; however, increase in the % RSD values observed for the between-day data was due to the instability of the drug in solution even at daylight reflecting its high protosensitivity. Satisfactory results were obtained for the assay and recovery testing with % RSD value well below 2. No interference was observed from the excipients in the formulations.

Thus the developed HPLC method was validated as stability indicating method for separation and quantification of Danazol in presence of its photodegradation products and can be used to determine Danazol in pharmaceutical formulation as well as in bulk drug.

H_1 Sensing residual antibiotics in field samples using genetically engineered bacterial biosensors

Joy Scaria*, Fabian Davamani, Harvinder Singh and S.K.Verma

Centre for Biotechnology, Biological Sciences Group, Birla Institute of Tech and Sciences, Pilani 333 031

Overuse of antibiotics for medicine and agriculture has resulted in the presence of residual concentrations of antibiotics being continuously present in environment and thus enabling antibiotics to act as Darwinian selective agents, killing susceptible organisms and allowing the expansion of the drug resistant variants in the population. The residual antibiotics in environment eventually undergo biomagnification causing emergence of multidrug resistance. However there is no mechanism of detecting and monitoring the residual drugs in field samples. In this context we have developed a novel sensing system for detection of residual concentrations of antibiotics in field samples using whole cell bacterial biosensors. A whole cell bacterial biosensor is a bacterium expressing a reporter gene Green Fluorescent Protein (GFP), in response to a stimulant in a concentration dependent manner.

We developed the novel biosensor strain by cloning tetR-tetA promotor sequence from plasmid pOT182 onto Enhanced Green Fluorescent Protein gene (EGFP) in plasmid pEGFP-1 and transforming E .coIDH5a. using this chimeric plasmid. Fluorescence emission by the biosensor strain was measured using Flow cytometry and the fluorescence emission varied with antibiotic concentrations in samples. The biosensor bacteria thus constructed can be exposed directly to sample, require no complex membrane systems to separate the sensing element from the background chemicals, allow non-invasive analysis without addition of any substrates and does not suffer from background problems. A cocktail of biosensor strains can be used to detect, the presence of one or more antibiotics and multiple samples can be processed simultaneously. This system has further have advantage over conventional antibiotic detection protocols by virtue of its rapidity

H_2 Production of murine monoclonal anti-bodies and evaluation of its efficacy in drug targeting for lung adenocarcinoma

Dhanaraj.S.A[1] Venkatesh.S[1], Saravanan.D*[1], Vijayan.P[1], Suresh.B[1] L.N.Rao Bhau[2], S.Shiva kumar[2].

1. J.S.S College of Pharmacy, Ootacamund, Tamil Nadu
2. Pasteur Institute of India, Conoor, Tamil Nadu

The conventional therapy fails to cure cancer effectively due to the distribution of the drugs to various organs apart from the cancer site, which leads to killing of normal cells other than the tumour cells. Hence it is important to develop an effective targeting system which allows selective damage to the cancer cells. One of the most promising approaches is the use of monoclonal antibody to deliver the drug at the target site (active drug delivery).

A hybridoma, which secretes MAbs against lung adenocarcinoma,was established from the hybrids of Balb/c mouse splenocytes immunized with A-549 (lung adenocarcinoma) Cell line and the mouse myeloma cell lines NS_1, according to the methods described by (Kohler and Milstein, 1975). The positive clones producing antibodies were screened by Elisa. The MAbs were purified from the hybridoma supernatant by ammonium sulphate precipitation and protein-A affinity chromatography.

Drug targeting was done by preparing albumin microspheres (MS) incorporated with the anticancer drug mitomycin c (MMC). The immunomicrospheres (IMS) were prepared by conjugating the selected batch with the mouse MAb .The ideal batch containing 25mg of drug was selected among the 10mg, 15mg, 20mg and 25mg batches for in-vitro and in vivo cytotoxic studies. The cytotoxicity produced by MMC-IMS batch on A-549 was much greater (89.47%) when compared to the MMC-MS (46.15%) and also the %increase in lifespan was more in MMC-IMS treated mice compared to MMC-MS and free MMC treated batch. Finally the histopathological studies on the lungs showed that MMC-IMS has better antitumor activity than other batches.

H_3 Molecular characterization of 6.5 kb plasmid of *shigella dysenteriae type1* its involvement in drug resistance and protein synthesis

Harish Rawat[1] Sameer Bhargava[1],Abhishek Gupta[1], Ajay Kumar[1] Kosy Kymonil[1] , Vivek Saraswat[1] Aarti Gupta[2] and Firoz Anwar[1]*

1. Department of Pharmaceutical Sciences, Shri Guru Ram Rai Institute of Technology& Sciences, Patel Nagar, Dehra Doon - 248001. India.
2. Trinity Pharmaceuticals, Ranwar Road, N/O Merrut Road, Karnal (Haryana), India

The present work characterizes a 6.5 kb plasmid of the Indian epidemic isolate *Shigella dysenteriae type1* (Dt66) in relation to virulence and

protein synthesis. Curing of the plasmids of Dt 66 strain by acriflavin (AF) yielded seven groups of AF cured derivatives. One of group of the AF cured derivative of Dt 66 strain contained 4 plasmid (120 , 6.5, 4.5 and 2.5) as against 6 (120-2.5) in the wild type Dt 66 showed resistance to Ampicillin, Chloramphenical, Norfloxacin and Streptomycin (Am^r, Cm^r, Nor^r, and Sm^r) but sensitive for the Nalidixic acid (Nal^s). This derivative when used as a donor in mating experiments with plasmid less E.Coli K 12 Kl 318 strain (Sm^r and Nal^r as a recipient, transferred only its 6.5 kb plasmid into the recipient with concomitant transfer of the Chloramphenical resistance (Cm^r) phenotype. Both the donor and transconjugant exhibit adherence and protein synthesis. Keroconjuctivitis test were seen positive when tested with Guniea pigs. The results sugest that 6.5 kb plasmid of Dt 66 strain encodes the Chloramphenicol drug resistance character along with synthsis of IPA proteins which is one of the major proteins in adherence of the organism to the human cell.

H_4 A new streptomycete species - *Streptomyces maduraensis* from soils of andhra pradesh

P. Ellaiah* and V.S. Venkateswara Rao

Pharmaceutical Biotechnology division, Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam-530 003 A.P.

*V.L. College of Pharmacy, Raichur - 584 103 Karnataka

During our continuous search for antibiotic producing actinomycetes, a new Streptomycete species was isolated from a soil sample collected at Maduravada near Visakhapatnam. It produces both intracellular and extra- cellular antibiotic principles active against Gram +ve and Gram -ve bacteria. The present investigation deals with the taxonomic studies of the isolate. The sporophores occurred as spiral spore chains. The aerial mycelium was light brown to brown to gray and light brown to pale gray to gray vegetative mycelium. It was non-chromogenic, H_2S and tyrosinase negative. It exhibited good diastatic activity. It could hydrolyze casein and gelatin and it could coagulate and peptonize milk. It exhibited good growth on arabinose, mannitol and rhamnose and showed poor to moderate growth on glucose, meso-inositol, sucrose, xylose and fructose. With reference to nitrogen source, good growth was observed on L-arginine, KNO_3, L-asparagine, poor to moderate growth on L-valine, L-histidine & L-cysteine HCl. It exhibited resistance against penicillin G & cephalexin and sensitivity to streptomycin, tetracycline, gentamicin & rifampicin. The cell wall composition showed the presence of LL-DAP and glycine indicating, it belongs to type-I while galactose and arabinose being diagnostic sugars. The morphological, cultural, physiological and biochemical characteristics of our isolate were compared with that of the reference strains reported in the literature which indicated that our isolate has differed significantly from the reference culture in many respects. Hence it is considered as a new species and designated as Streptomyces-maduraensis sp.nov. The isolation and purification of antibiotic principles are under progress.

H_5 Characterization of mixing intensity on the production of urokinase by AUB 101 cell line in a bioreactor

P. Ellaiah, V. Saisha, P. Vasu, M. Sunitha, G. Divakar, K.V.V.S.N. Bapi Raju and P.Udaya Shankar

Department of Pharmaceutical Sciences,Andhra University, Vishakapatnam 530003

Urokinase(UK), is a life saving, therapeutically important fibrinolytic enzyme used in treatment of deep vein thrombosis, thrombosis of the eye, pulmonary embolism, myocardial infarctions, and many other disorders requiring dissolution of blood clots.

Studies on mixing efficiency in bioreactors for the production of UK using a human kidney cell line AUB101 isloated from kidney biopsy tissue of MPGN patients were carried out. The mixing time represents one of the most useful criterion for characterization of mixing intensity and for biosynthesis processes scale up.The mixing time, t_m is defined as the time needed to reach a given mixing intensity at a given scale when starting from the completely segregated situation. Studies on the determination of mixing time and the dependence between the mixing time ,rheological characteristics and medium conditions for urokinase production were carried out in laboratory bioreactor (B.Braun Biotech International) with computer control and automated recorded parameters.

The results indicated that increase in broth viscosity with increase in biomass or biosynthesised product accumulation leads to increase in mixing time. In the case of single stirrer system, mixing time was high compared to that of two stirrer system.

By means of experimental data and using multiregression analysis method a mathematical model which describes the mixing intensity through mixing time was developed using MATLAB program.

H_6 Studies on bioprocess parameters for the production of thermostable cyclodextrin glycosyl transferase (CGTASE) from a newly Isolated Streptococcus SPS

T.Prabhakar, P.Ellaiah, V.Saisha, P.UdayaShanker, G.Divakar, R. Bhavani Devi and M. Anitha Rao*.

Department of Pharmaceutical Sciences,, Andhra University, Vishakapatnam 530003

Cyclodextrin Glycosyl transferase (CGTase) catalyzes the degradation of starch to form cyclodextrins. The β-form of cyclodextrins is reported to be more suitable for industrial use because the inclusion complexes are easily prepared and very stable due to their low solubility in water. Enzyme CG Tase with different properties have been found in several micro-organisms i.e. *B.macerans, B.circulans, B.megaterium , B.stearothermophilus, K.pneumonia, B.obhensis* and *alkalophillic Bacillus sps.* Screeining of soil samples was carried out for isolation of active CGTase producers. 43 colonies were isolated, a potent CGTase producer was selected and assessed for CGTase activity by the modified procedure of FUWA (1954). The CGTase production was carried out by submerged fermentation technique (SmF). The assay of cyclodextrins by the PHE method was used in order to confirm the presence of cyclodextrins in the fermented broth. Morphological, cultural and biochemical tests were carried and identified as a strain of *Streptococcus.* (B13). Solid state fermentation, (SSF) process was also employed. The strain grew optimally at 37°C and produced 0.354 U of CGTase/ml in SmF and yield increased to 38.725 U/g BB in SSF. Nutrients screened by Plackett - Burman design, proved to be useful in increasing the yield of CGTase by 161.35%. Purification of the enzyme was carried out by using Sephadex G-50 gel filtration chromatography and sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE). Activity of CGTase after purification with chromatography increased by 25-fold.

H_7 Effect of permeabilizing agents on production of indole alkaloids from *Catharanthus roseus* cell cultures

Sathish B, Gaviraj EN*, and Veeresham C**

Medicinal Plant Biotechnology, UCPSc, Kakatiya, University, WARANGAL-506 009, AP, India.

Cell cultures of *Catharanthus roseus* may be an alternative source of therapeutically important alkaloids like ajmalicine and vincamine. But these secondary metabolites are accumulated inside the cells in very low amounts. The productivity of such cultures can be improved by cell permeabilization, which not only facilitates product recovery but also favours the further biosynthesis of plant metabolites. Cell cultures of C. roseus were treated with different concentrations of various permeabilizing agents like cetrimide, chitosan, triton X-100 and DMSO. All the permeabilizing agents used in the present study showed an increase in the bioproduction of ajmalicine both in cells and medium when compared to control cultures. The maximum amount of ajmalicine was detected on the addition of cetrimide (60 ppm). There were 14- and 20-fold increases of ajmalicine in cells and medium respectively, when compared to control cultures. An interesting finding was the capability of our cell cultures to produce vincamine, which is widely used as a cerebral vasodilator. The maximum amount of vincamine was detected on the addition of cetrimide (60 ppm) and DMSO (4% v/v). There were 10 – fold increases of vincamine in cells and medium respectively, when compared to control cultures. The present study shows that permeabilizing agents can be effectively used to improve the secondary metabolite production in cell cultures of C. roseus.

H_8 Bioremediation of copper using dead biomass and immobilization techniques

Mithun*, A.S. Willams, J. Bagyalakshmi, T.K. Ravi

College of Pharmacy, Sri Ramakrishna Institute o Pharmaceutical Sciences, Coimbatore 641 044, TN

Bioremediation is the use of biological treatment systems to destroy or reduce the concentrations of hazardous waste from a contaminated site. It includes process of biosorption as well as bioaccumulation. Biosorption commonly refers to the passive binding of metal ions by biomass, which may even be dead. It must be distinguished from bioaccumulation, which is usually understood to be an active, metabolically mediated process occurring in living organisms.

The present study was aimed to find out the copper removal capacities of three organisms namely *Saccharomyces cerevisiae, Pseudomonas aeruginosa* and *Candida albicans* under two different conditions dead as well as immobilized states. The whole procedure was carried out at optimum temperature of 30°C and pH of 5.

The biomass obtained by centrifugation of the cultures of micro organism were dried at 60°C for 2 hrs. The dead biomass was then treated with known concentration of copper (200 m gm) and rate of adsorption was found out.

With respect to immobilization it was done in three different ways.

a. Using brick particles

b. Using 3% sodium alginate

c. Using carragennan

On the whole when the results were compared *Saccharomyces cerevisiae* was found out to accumulate maximum amount of copper from the aqueous solution and immobilization with brick particles was found to be the best method. It accumulated around 97% of copper after a contact time of 24 hrs. That the organisms were suitable for copper removal was further proved by freundlich and Langmuir isotherms.

H_9 Interaction of cytotoxic compounds on microtuble dynamics in Hep-2 cells.

S.A. Dhanaraj, P.Vijayan, T.S.Shanmugarajan, P.S Madankumar, Rajesh Patel* and B.Suresh.

Department of Pharmaceutical Biotechnology, J.S.S College of Pharmacy, Ooty-643 001.

Preventive remedies against many cancers have not been well developed. Natural products such as vinca alkaloids, colchicines, taxanes were used as anticancer agents due to their interaction with microtubules, integral components of the cytoskeleton of the cell, but their potential is limited due to development of multi-drug resistance (MDR). So, we were interested to synthesise some synthetic compounds having good antimitotic activity.

We selected five synthetic compounds (I-V) for their cytotoxic and antimicrotubular studies. Cytotoxic effects of compounds were determined by dye exclusion technique, micro cultured tetrazolium (MTT) assay and sulphorhodomine B (SRB) assay against both normal cell line (vero cell line) and cancerous cell line (Hep-2 cell line). The 50% cytotoxic concentration (CTC_{50}) was determined for all compounds. All the compounds tested for their cytoxicity were showing higher toxicity to the cancerous cell line than normal cell line. Hence we selected Hep-2 for further antimicrotubular studies.

To evaluate whether the antiproliferative activity was due to apoptosis, we analysed DNA fragmentation. All compounds were treated with Hep – 2 cells, so typical DNA fragmentation pattern was observed for all the compounds. We performed indirect immunofluorescence studies with Hep – 2 cell line for DAPI to stain chromosomes, in that all compounds except III were exhibiting good activity against spindle formation during metaphase in mitosis. The effect of cytotoxic compounds upon microtubular organisation was investigated by fluorescence microscopy.

Hence it concluded that all five tested synthetic compounds were showing good antimitotic activity, but among these the compound IV 1-phenyl-3- (3-nitrophenyl)-2-propen-1-one was the most potent microtubule inhibitor (CTC_{50} 49.18 mg/ml).

H_{10} Lectinized Liposomes Bearing an Antimicrobial Agent as a Therapeutic Arsenal for Bio-film Targeting (Preparation and Characterization)

Sudheesh M.S*[1], Shailendra L[1], Venkatesan J[1], Umasankar K[1], Jain A.K[2], Kohli D.V[3], Vyas S.P[3].

1 Sanjivani College of Pharmaceutical Sciences, Khetri, Rajasthan.

2 B.R.Nahata College of Pharmacy, Mandsaur, M.P.

3 Department of Pharmaceutical Sciences, Dr. H.S.Gour University, Sagar,

A bio-film is a population of cells growing on a surface and enclosed in a exopolysaccharide material. Bio-films are notoriously difficult to eradicate and are a source of many recalcitrant infection. Recent advances in once understanding of the genetic and molecular basis of bacterial community behavior points to therapeutic targets that may provide a means for the control of bio-film infection until recently most investigation have been performed on planktonic (floating or fluid phase) microorganisms. After realized of bio-film existence and then recalcitrant towards conventionally adopted preventive strategies and antimicrobial agents, research has been shifted towards novel therapeutics based drug delivery and targeting approaches. In the present study ligand anchored Dried Reconstituted Vesicles (DRVs) containing fluconazole were prepared. The DRVs consisting of soya phosphatidylcholine (SPC) cholesterol (Chol) and stearoylamine containing fluconazole were prepared. These vesicles were then covalently anchored with concanavaline-A (Con-A) with carbodiimide (EDC) as a coupling agent. Since Con-A is alectin (a protein) this process is called lectinization.con-A is specific for glucose and mannose residue on the fungal bio-film an dthus helps in the targeting of liposomes to fungal cell surface. Coated vesicles were further characterized for there ligand affinity and activity with bovine sub maxillary gland mucin(BSM). BSM consists of six different sugars. The developed systems were then assessed for there targeting potentials by a microtitre plate assay. Bio-film of Candida.albicans was developed on a microtitre plate. Various allquots of ligand anchored liposomes, their plain counterparts and free drug were then incubated wiyh the develop bio-film and absorbance were studied colrimetric method. The parameters studied were % bio-film inhibition and lectin target enhancement(LTE). Results show an enhanced bio-film growth inhibition and LTE with the lectinized liposomes which was due to the specificity of the lectin for the exopolysaccharide on the bio-film surface.

H_{11} Anticarcinogenic effects of *Cyanodon dactylon* and *Coleus aromaticus* in DLA/ EAcell lines

R.Parimala*,Suneethavelangapudi[1],Annapoorani S[1]. Abhay, Dharmsi and P.Balasundari

*KMCH College of Pharmacy, Kovai Estate, Kalapatti Road, Coimbatore-35.

1. Department of Biochemistry and Biotechnology, Avinashilingam Deemed University, Coimbatore 641 043.

The polyacrylamide gel electrophoresis eluted protein fractions of the plant leaves of Cyanodon

dactylon (arugampul) and Coleus aromaticus (karpuravalli) was investigated for its cytotoxic, antioxidant and antilipid peroxidative and xenobiotic destroying enzyme activity.In vitro experiments have shown tha tdose dependent cytotoxic effect using Dalton's lymphoma ascites (DLA) and Ehrlich ascites (EA) cell lines. Followed by in vivo studies using DLA cell lines in Swiss albino male mice showed that a significant enhancement of enzymic, non-enzymic antioxidants. Induction of xenobiotic enzymes and inhibiion of lipid peroxidation. These investigations of the protein eluates showed good antioxidant activity thereby supporting anticarcinogenic properties.

Last few decades there has been exponential growth in the field of herbal medicine, it as getting popularised in developing countries and developed countries owing to its natural origin and lesser side effects[1]. Environmental factors such as smoking, diet and pollutants play role in most human cancer[2]. Therefore, factors that prevent activation of carcinogens and or increase their detoxification become important as protective agents against cancer[3]. In vitro studies has also revealed the toxic effect of the cytotoxic function in Ehrlich Ascites tumour cells and provides evidences for multinucleosomal DNA fragmentation characteristic of apoptosis[4]. Antioxidants are natural defense mechanisms existing in our system and these are capable of scavenging the deleterious free radicals[5] . Proteins called cyclins, must disappear for the cell cycle to proceed through cell division by allowing cyclin build up which arrest cell division and halt tumour growth [6].

H_{12} Insilico modeling of 3D structure of resistin

S.L.N.Prasad Reddy[a*], T.Prabhakar [b], K.S. Rajesh[a]

a. Krupanidhi college of Pharmacy,Sarjapur Road, Koramangala, Bangalore

b. Department of Pharmaceutical Sciences, Andhra University, Vishakapatnam.

Resistin, a unique signaling molecule which involves in type-II diabetes and is secreted by adipose tissue. The human resistin consists of 108 amino acid residues and presumed that it negatively modulates the action of the insulin. To understand the molecular mechanism of resistin, the structure of this protein should be known. Since the structure is not known, an attempt is made to model its structure. General properties of resistin are assessed by submitting its sequence to Protoparam and Protascale. The structure of resistin is modeled by using Modeller 6v.1 and Swiss PDB viewer is used to refine the modeled structure .The refined structure is evaluated by using Verify3D and Procheck. The primary sequence of resistin was submitted to SignalP server to find its signal Peptide and also subjected to PSORT, a protein localization server to determine its localization. It is predicted that N-terminal of resistin starts with highly hydrophobic amino acids and has conserved pattern of Cysteines at the C-terminal, like any other members of FIZZ family. It is hypothesized that resistin has N-terminal signal sequence with highly hydrophobic amino acids and is localized extracellularly. Hence it may be exerting its action through a surface receptor, which may negatively regulate insulin signaling pathway and cause type-II diabetes.

H_{13} Fermentative production of lipase and its immobilisation using sodium alginate

*** Sreejith C.R, Sarif Niroush. K, P. Arulraj, Y. Haribabu**

R.V.S. College of Pharmaceutical Sciences, Sulur, Coimbatore 641 402

Keeping in mind the ultimate goal for the pure commercial production enzymes from different microbial and animal sources, we have produced enzyme lipase with a commercially available microorganism *Pseudomonas aeroginosa*.

The increasing awareness of immobilization of the enzyme has stimulated us to convert the free enzyme into immobilized beads.

Among the methods currently used for the immobilization of enzyme we fall on the same called gel entrapment techniques, appear from this we have monitored and optimized the fermentation condition by changing the temperature, duration and pH of the fermentation medium.

H_{14} Inhibition of nitric oxide production by extract of latex of *Calotropis procera* in endotoxin inducted *in vitro* septic shock model

[1]Nitika Kaushal*, [2]Hridayesh Prakash, [3]H.C.Goel, [4]Suresh Kumar.

1,4 GGS Indraprastha University, Kashmere Gate, Delhi-110 006.

2,3 Institute of Nuclear Medicine and Allied Science, Lucknow Road, Timarpur, Delhi-110 054.

Septic shock is defined as an overwhelmed systemic inflammatory response to infection, which is associated with fever, hypotension, disseminated intravascular coagulation, multiple organ dysfunction and ultimately to death. Septic shock arises in situations such as postoperative surgeries, organ transplantation, burn cases and in cases of rheumatoid arthritis. Endotoxin (Lipopolysaccharide/ LPS) is the

main culprit molecule responsible for initiating the responses associated with sepsis, which in turn interacts with CD14, a cell surface receptor present on macrophages. This interaction activates the cell for the production of various inflammatory mediators such as TNF-a, IL-1, IL-6, and Nitric Oxide. The overproduction of nitric oxide is implicated in the pathogenesis of septic shock leading to vasodialtion, fall in blood pressure, circulatory collapse and hypotension. In our study, we evaluated the crude aqueous extract from the latex of *Calotropis procera* and screened its inhibitory activity on nitric oxide production in LPS stimulated murine macrophages. Our finds showed that the concentration of crude extract ranging from 250 mg/ml to 15.625 mg/ml, selectively inhibit the nitric oxide production in peritoneal macrophages. The nitric oxide produced in LPS control group was 66.49 mmol, which was reduced to 5.63 mmol when treated with the extract at a concentration of 15.620 mg/ml. We conclude from our study that the crude extract of *Calotropis procera* selectively blocked the nitric oxide production and in future may be explored for the development of a suitable and efficient mechanism based therapeutic approach in septic shock.

H_{15} Thermostable protease producing Thermoactinomyces sp. strain improvement studies

P.Ellaiah, Divakar Goli1 , Kalyani Divakar[1], V.Saisha, M.Sunitha, and K.Udaya Shankar

1. Acharya & BM Reddy College of Pharmacy, Peenya, Bangalore 560058

Dept. of Pharma. Sciences, Andhra University, Visakhapatnam 530 003.

Actinomycete proteases are similar in action to mammalian proteases and find major application in the food industry for protein liquefaction, milk clotting or as meat tenderizers. Some proteases of actinomycete origin are highly resistant to heat and denaturing agents. The high thermostability of proteases isolated from thermophilic actinomycetes is well known. Two strains of Thermoactinomyces sp. (PE-23 and PE-120) were isolated in our laboratory and subjected to UV irradiation. The mutants obtained (59 nos.) were tested for their ability to produce high yields of proteases. Four mutants (two from each parent strain) were further treated with Ethyl Methyl Sulfonate and 28 mutants were isolated. Among these, a mutant PEE-05 was found to be yielding high amounts of alkaline protease (248U/ml), an increase in protease productivity by 100% than the parent strain (124 U/ml).

Further it was assumed/suggested that high productive mutant obtained by one method may not be able to produce another mutant with increased productivity. A mutant with less productivity may be further mutated by another mutagen to give high producer of enzyme.

H_{16} Isolation, identification, mass production and preservation of *Lactobacillus acidophilus*

R.K. Patel*, P.A. Nagar, M.M. Patel K. Pundarikakshudu

S.K. Patel College of Pharm. Edu. & Res., Ganpatvidyanagar, Kherva, Mehsana- 382 711, Gujarat.

Lactobacillus acidophilus is a member of *Lactobacillus species*, a group of Gram positive non sporing micro aerophilic rods that are indigenous inhabitants of the human intestine and vagina. The main role of *L. acidophilus* in the gastro intestinal tract is to reinforce the protective barrier of the mucosal surfaces and to prevent the attachment of pathogenic microorganisms. They metabolize carbohydrates and produce lactic acid, acetic acid, hydrogen peroxide and short chain fatty acids. They also produce inhibitory substances called bacteriocins that kill microbes and bacteria. Lactobacillus acidophilus also produce lactase, the enzyme that breaks down milk sugar (lactose) to glucose and galactose. This phenomenon has immense significance in lactose intolerant patients.

Looking at the beneficial properties of *Lactobacillus acidophilus*, the work was carried out for the isolation of these bacteria from various local sources, to identify the correct strain through various cellular, colonial, and biochemical characteristics and to develop ideal preservation and maintenance techniques for the viability of isolated strains of Lactobacillus acidophilus. Mass production of the Lactobacillus acidophilus was also carried out using Man, Rogosa, Sharp (MRS) liquid medium containing glucose as a primary source of carbon and energy. Effect of different concentrations of each ingredient of the MRS medium and utilization of different sugars on the yield of Lactobacillus acidophilus was studied.

Curd was the best source of Lactobacillus acidophilus from among the four sources screened. Isolated cultures have the typical features of Lactobacillus acidophilus. The results obtained after optimization of the concentrations of the ingredients of MRS medium revealed that glucose in the concentration of 3.0 % gave maximum yield of the L. acidophilus. Whereas growth experiments with Beef extract, yeast extract, peptone, Na acetate, K2HPO4, tri-ammonium citrate revealed that they are optimum in concentrations as mentioned in original composition of MRS medium. $MgSO_4$ and tween-80 did not affect the growth of Lactobacillus acidophilus in any concentrations they were utilized. $MnSO_4$ is essential in very low concentration. The yield of the Lactobacillus acidophilus in optimized MRS medium was found to be 3.0 X 10^9 cells/ml.

Growth experiments in Glucose, yeast extract, peptone (GYP) medium gave the yield of 1.85 X 10^9 cells/ml of L. acidophilus which revealed that ingredients of MRS medium other than glucose, yeast extract and peptone account for only 10 % increase in the growth.

Excepting lactose, all the other sugars studied were found to be equally efficient for the growth of Lactobacillus acidophilus.

Preservation in MRS agar slants and under liquid paraffin at 4ºC found to be both ideal and practicable for preservation of Lactobacillus acidophilus.

H_{17} Biotechnology and biotech derived products: current status in India

S.S. Poddar, R.K. Dube, Milina Vaswani*, J. Panjawani.

K.M. Kundnani College of Pharmacy.

Biotech is the biggest upcoming field in India affecting major areas in agriculture and pharmaceuticals. Biotech is proved to be the major area of research globally. Objective of the work was to go into details of ground realities through surveys.

Work was done by carrying out a face-to-face interview using a predesigned questionnaire. Also an attempt has been made to propose suggestions that would uplift the Indian biotech status.

Data obtained analyzed graphically and statistically showed that 18 out of 100 companies in biotech sector invest upto 12% of total funding that goes into product development . 70% agreed that investments were going in wrong hands. 72% respondents agreed upon the fact that companies do not invest in biotech-derived products due to unclear government policies.

Hence we come to a conclusion that India is in a state of confusion as to what should be its role in development as far as global picture is concerned.

Agreement is sought about the fact that biotech is definitely an upcoming field and soon it will infect each and every strata of science.

In future work is to be done to clear government policies. We should put effort in the direction to see conventional pharmaceutical and biotech derived products at the same level in all respects.

For this to happen a survey at national level should be carried out for finding out the root cause of such a slow growth.

H_{18} Production of lipase by solid state fermentation using sugarcane bagasse as a support employing fractional factorial design

T. Prabhakar, P. Ellaiah, V. Asha Ranjani, K.V.V.S.N. Bapi Raju, M. Sunitha, V. Saisha M. Uma, P. Uday shanker and G. Divakar

Department of Pharmaceutical Sciences ,Andhra University, Vishakapatnam 530 003

Microbial lipases have a panoramic use in biotechnological process. Lipases are one of the primary metabolites abundantly available in microbial world. A few lipolytic fungi were isolated in our lab and extensive studies were conducted. A promising isolate with good lipolytic activity was selected and subjected to taxonomic studies. It was identified as *Aspergillus sp.* and designated as *Aspergillus AS-11*. In the first phase, lipase production was carried out with SmF and an optimized medium was formulated. The composition of optimized medium used in this study was glucose 2%, ammonium sulphate 0.5%, magnesium sulphate 0.2%, salt solution 5%, olive oil 1%, tween 80 0.16%. In view of several advantages associated with SSF over SmF and because of economic feasibility SSF was adopted for the production of lipase employing our isolate, Aspergillus AS-11. Some of the physical and chemical parameters optimized were moisture content found to be highest at 80%, 2ml level of inoculum shows the optimum activity, 30-40 mesh size was considered to be optimum, highest activity of temperature between 20-30°C. The initial yield of lipase in SmF was 1.90 U/ml while the yield in SSF was 2.19 U/ml an the yield in optimized medium was found to be 2.58 U/ml which accounts about 20% increase in lipolytic activity employing Fractional Factorial Design (FFD). The strain AS-11 was subjected to UV irradiation, six isolates were selected and studied for their lipase production by SSF. Among these strain AUV4 exhibited the highest productivity of 3.32 U/ml and enhances the yield of (58%) lipase production.

I_1 A study on patient compliance and their response towards prescriptions in an out-patient clinic

SB Bhise[1], Amit Gupta[2].

1. Govt. College of Pharmacy, Aurangabad.
2. Govt. College of Pharmacy, Karad (M.S.).

The investigation presents a brief report of the study which was carried out in an out-patient clinic (OPD) situated in Bolieauganj, a suburb in Shimla town (Himachal Pradesh), for assessing the level of patient compliance to medical regimen, reasons for partial/non-compliance and their response to the prescriptions. Consumption of all the essential drugs by the patients was considered as full compliance, while consumption of few or none of the essential drugs was considered as partial or non-compliance respectively.

A questionnaire was prepared and out of the total of 3594 new OPD cases, 235 patients were selected, at each follow-up compliance was assessed and total compliance was evaluated, which reveals the following results:

- The rate of full compliance was 67.1%, partial compliance was 32.5% and for non-compliance, it was 0.4%.
- Major reasons for the compliance failure were side effects (35.8%), forgetting to take the dose (20.5%), bad taste (13.5%) and time adjustments (9.2%).
- When the patients were assessed for their response towards prescriptions at the first follow-up, it was seen that:
- Full compliance rate was high when less drugs were prescribed (81.2%), prescription was understandable (78.2%), treatment was effective (78.4%), drugs were identifiable (70.5%) and drug administration was simple (69.7%).
- Partial/non-compliance was seen when more drugs were prescribed (67.4%), prescription was difficult to understand (61.4%), treatment was ineffective (81.4%), drugs were unidentifiable (69.0%) and drug administration was difficult (85.2%).
- With the present study, we conclude that to improve the rate of patient compliance, doctor and pharmacist should work together hand in hand. A doctor should prescribe minimum adequate number of drugs with simple and effective regimen. A pharmacist should educate the patients regarding their prescription and dosage of drugs.

I_2 A study of antibiotic suceptibility and incidence of urinary pathogens in an urban area

Ghaisas M.M.*[1], Limaye R.P.[2], Patil J.J.[1], Pathan A.D.[1], Zambad S.P.[1], Deshpande A.D.[1]

1. Dept. of Pharmacology, Padmashree Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune – 411 018.
2. Pravara Rural Medical College, Loni, Pravaranagar, Ahmednagar.

There has been a tremendous rise in the incidence of development of resistance to commonly prescribed antibiotics in the urinary tract infections. Hence there is a need for the information about the local resistance patterns as well as epidemiological trends in resistance to antimicrobial agents.

The retrospective study was undertaken during 1st January 2002 to 31st December 2002, for the purpose of studying the recent pattern of antibiotic susceptibility and incidence of urinary pathogens using total 1008 samples received in four private pathology laboratories from Pimpri- Chinchwad, Pune (India).

In the present study, it has been observed that the most commonly found urinary pathogens are E. coli (62.1%), Proteus species (8.53%), Klebsiella (10.81%), Pseudomonas species (6.4%) , Streptococci (4.66%), Staphylococci (5.95%). It has been observed that there has been alarming pattern of development of resistance to the commonly prescribed antibiotics in the urinary tract infections namely Amoxycillin, Ampicillin, Nalidixic acid, Ciprofloxcin and Norfloxacin. The most commonly found urinary pathogens *E. coli , Proteus species, Klebsiella, Pseudomonas species, Streptococci, Staphalococci* showed more sensitivity to Cefotaxime than Amikacin, followed by Netilmycin, Ceftriaxone, and Gentamicin. Though most of the common pathogens have the ability to develop resistance against the antimicrobial agents, the overuse of antibiotics has continued. This indiscriminate use of antibiotics may be probable reason for observed pattern of development of resistance.

I_3 Prospective study of poisoning cases at KLES's hospital and medical research centre, Belgaum

M.S. Ganachari, George Mathew, Sachin*

Dept. of Pharmacy, Annamalai University, Annamalai Nagar 608 002, TN

In spite of various advanced in medical practice poisonings due to various reasons continue to be major issue with significant morbidity and mortality. It forms

significant percentage of admissions in hospital. This study was undertaken to assess the various modes of poisoning, morbidity, morality and various other parameters in patients admitted in K.L.E.S's Hospital, Belgaum.

127 patients admitted for poisonings were evaluated in this study. All patients were included irrespective of whether it was suicidal ingestion, accidental or occupational along with the snakebites. Food poisoning were excluded.

57.5% of patients were male, however male to female ratio varied with different agents. Maximum age group was under 20-30 years (31.5%). Occasional case in old age also occurred. 56.7% had ingested with suicidal intent. 24.4% accidental, 12.6% occupational and unknown 6.3%. 37.8% of patients were those of organophosphate poisoning, 8.66% other pesticides and rodenticides ingestion, 6.29% household products, 22% to drug overdose. 13.38% parenteral poisoning (snake bite and stings) and 5.5% were due to unknown/ miscellaneous agents. Illiterate, lower income group consumed more poison compared to other groups. In pediatrics, accidental poisoning was common.

12.5% patients died, mortality varies with various agents ingested. Maximum death (50%) with organophosphate, snakebite and drug over dosage had very low mortality. More time between poisoning and hospitalization caused the maximum mortality. Financial difficulties, family disputes, unemployment were the major stress factors for suicidal poisoning.

Maximum interventions made to post graduate students (65.15%) about the poison, antidotes and management.

The fundamental dictum is "Prevention is better than cure", so maximum poisoning can be avoided by educational campaign, psychological counseling and strict vigil on pesticides. Requirement of protocols for the poisons management shows the need of Poison Information Centre for immediate and detailed advice.

I_4 Effect of inhaled salmetrol and fluticasone and impact of patient education on quality of life on exacerbation of asthma

A.R.Shabaraya*[1] , B. Suresh [1]., S.D Rajendran[1]., Vishnusharma M[2].

*NGSM Institute of Pharmaceutical Sciences Nantoor.,Mangalore.,

1. JSS College of Pharmacy, Ooty., 2. Justice K.S. Hegde Medical academy, Mangalore.,

Inhaled Glucocorticoids are considered the first line treatment for patient with moderate to severe persistent asthma. Many studies have proven that patient education improves the understanding of patient's asthma, which in turn improves the treatment outcome and quality of life.

In a parallel study we evaluated the impact of patient education and quality of life in patients inhaled salmeterol 50 mcg and Fluticasone 200/100 mcg on exacerbation of asthma.

Physician diagnosed and confirmed adult asthma patients who received inhaled salmeterol 50 mcg and Fluticasone 100/200 mcg were included as per study criteria. Pulmonary function was tested using Spirometer and patients were reviewed by the end of 2nd, 4th, 8th, 12th, and 16th week from the base line and PEFR and FEV_1 were recorded. Patients were randomly divided into study and control groups and patient education has been provided to the study group. T test was used to find out the significance of the results. The change in the percentage predicted value of PEFR were found to be 52.65+13.3 to 87.88+10.78 in study group and 50.14+13.45 to 74.27+ 13.91 in control group with t value 4.26 ($p<.05$).. The percentage predicted value of FEV_1were found to be 49.09+13.03 to78.07+10.78in study group and 48.47+13.92to 63.34+14.45 in control group with t value 4.60 ($p<.05$). The changes in AQLQ scores in pre and post treatment between study and control groups were found to be with the t value0.54 to 4.61 ($p<.05$). The significant difference in PEFR, FEV_1 and AQLQ scores ($P<.05$) in study and control group indicates the impact of patient education on quality of life.

I_5 Epidemiological dimension and control of drug resistance in tuberculosis

N.R.Pani*, D.M.Kar, S.K.Panda, S.B.Mukhi

Univ. Dept. Of Pharm. Sciences, Utkal University, BBSR, Orissa

TB remains a world wide public health problem despite the fact that the causative organism was discovered more than 100yrs ago, and highly effective drugs and vaccines are available making TB a preventable and curable disease. India unfortunately accounts for 1/4th of the global burden of TB.

This work aims at accessing the various epidemiological indices, role of pharmacist in patient compliance and control of drug resistance. Survey was done in the following manner.

- Collection of one yr (from Aug.02 to July03) data from six District Tuberculosis Centers (DTC) of Orissa to know the epidemiological indices.
- Interaction with 14 physicians and 17 trained technicians regarding various parameters of TB.
- Interaction with 64 patients regarding awareness, compliance to prescription etc.

- A deep study of the 175 casebooks to know the patient's history and causes of drug resistance.

The survey reveals that doctors at DTC still depend on X-ray diagnosis when it is well established that sputum microscopy is the preferred tool for pulmonary TB. The drug resistance however is the common medical error in the treatment of TB.

I_6 Trial implementation and assessing the impact of standard therapeutic guidelines in assistance with general practitioners of mysore city

Sameer Dhingra*, B. G. Nagavi and B.R. Nataraj

JSS College of Pharmacy, SS Nagar, Mysore - 15

Standard Therapeutic Guidelines (STG's) are a set of recommendations for the treatment of specific clinical circumstances. Many studies have shown that the successful implementation of therapeutic guidelines improves the quality use of drugs. It is important to develop valid guidelines by a sound methodology and ensure effective implementation of the same.

The primary objective of this work was to trial implement "Standard Therapeutic Guidelines for Primary health care", prepared by Department of Pharmacy Practice, JSS College of Pharmacy, Mysore, in selected private clinics of general practitioners (GP's) of Mysore city. The objective was also to assess its acceptance and impact on prescribing pattern of the general practitioners of Mysore city. A total of 1363 prescriptions before and 1043 prescriptions after were analysed. STG implementation was carried out by providing handbook of the STG and having individual educational interaction with general practitioners. After giving three months of implementation, prescriptions for the same selected diseases were analysed for assessing the impact of the guidelines. The total study duration was nine months and it was a prospective study. Primary outcome measures of the study were adherence with respect to the recommendations in the STG and effect on the WHO recommended prescribing indicators.

Study results showed an increase in appropriateness of treatment with respect to the recommendations in STG, for the parameters of choice of drug from 60% to 74%, dose from 57% to 73%, frequency of administration from 57% to 71% and duration of treatment from 48% to 59%. There was a significant increase in the amount of drugs prescribed from Essential Drug List (EDL) from 75% to 86%, which revealed an improvement in rational prescribing. There was a statistically significant change in average number of drugs per prescription. But there was no statistically significant change in other two parameters, percentage of prescriptions with an antibiotic and percentage of prescriptions with an injection. Analysis of general practitioners experience after using STG showed a positive attitude towards the guidelines. STG's were useful in improving GP's prescribing practices and thus improved patient outcomes. Pharmacist played a key role in trial implementation and improving rational prescribing.

I_7 Medication-prescribing errors in a public teaching hospital in chandigarh

***Pawar Shrikrishna B.[1a], Tiwari P[1b], Agarwal Vikas[2]**

1. Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, SAS Nagar, Punjab
2. Department of Medicine, Government Medical College & Hospital, Chandigarh.

Medication error is defined as "any preventable event that may cause or lead to an inappropriate medication use or patient harm while the medication is in the control of healthcare professional, patient or consumer". Error may occur during prescribing, dispensing, administration, monitoring and compliance. An error may be of many types such as wrong dose, route, dosage form, administration timing, patient, omission and so forth. A study conducted in the pediatric ward of an Indian hospital reported an overall medication error rate of 6-7% (prescribing errors-37%). This study was aimed to investigate the incidence & types of medication prescribing errors in a 400 bed capacity public teaching hospital.

The study involved the analysis of in-patient prescriptions selected randomly from internal medicine ward, and were reviewed. More specific details on the prescriptions were obtained by interviewing the clinicians, nurses, patient & their caretakers. One clinical faculty was also involved in reviewing the cases. All the errors observed were confirmed after discussion with the clinician before classifying as an error.

A total of 32 errors (out of fifty prescriptions reviewed) were found. The patients (average age - 45.6 yrs) were prescribed 7.7 drugs on an average. Common diseases observed were diabetes, hypertension and chronic renal failure. About 64% of prescriptions had atleast one prescribing error. The types of error found were overdose (25%), drug with no indication (25%), wrong administration timing (22%), duplication (13%), underdose (6%), contraindicated drug (6%), miscellaneous (3%). Most common medication classes involved were antibacterial (22%), cardiovascular (22%), gastro-intestinal (19%), vitamins minerals & electrolytes (16%), steroids (6%) and others.

Overdose, drug with no indication and wrong administration timings are the most common types of errors, whereas antibacterial and gastro-intestinal drugs were prominent drug classes found during the study period. The higher error rate may be associated with multiple drug therapy.

I8 A study of the prescribing pattern in diarrhoea patients in pediatrics in a teaching hospital

Elsy Susan Idicula*, Mohanta G.P, Radhakrishna A, Manna P.K, Manavalan R.

Dept. of Pharmacy, Annamalai University, Annamalai Nagar 608 002, TN

A study on the prescribing pattern in diarrhoea patients was carried out in the department of pediatrics in Rajah Muthiah Medical College and Hospital in the prospective manner. The prescriptions were analyzed for (1) various conditions associated with diarrhoea (2) age distribution of patients, (3) length of hospital stay, (4) average number of drugs prescribed per day, (5) percentage of drugs prescribed for essential drug list, (6) percentage of patients treated with antimicrobials, (7) percentage usage of ORS, (8) percentage usage of I.V fluids, (9) percentage usage of probiotics, (10) Average cost of therapy. A total number of 60 prescriptions were analysed in a period of two months. On the basis of dehydration, the prescriptions were classified into three categories (1) diarrhoea with no dehydration, (2) diarrhoea with some dehydration (3) diarrhoea with severe dehydration. Out of the 60 patients 20.45% were in the first category. 54.5% were in the second category and 25.05% were in the third category. 87% of the total patients were below two years, 9% in two to five years age group and the remaining 4% were above five years. Average length of hospital stay was found to be 5.22 days in the first category, 5.8 days in the second category, and 6.8 days in the third category. Average number of drugs prescribed per patient per day was found to be 4, 4.3, and 4.9 in the three categories respectively. 33% of the total patients in the fist category had infections and 87.5 % were treated with antimicrobials. In the second category 41% of patients had infections and 83% received antimicrobials. 63% of patients in the third category had infections, but antimicrobials were administered to all. 86% of the total drugs were prescribed from essential drugs list. Percentage usage of ORS was found to be 62.5%, 75% and 50% respectively in the three categories. I.V fluids were used in all the cases of severe dehydration, 95% in second category and 55% in the first category. Probiotic usage was found to be 87.5%, 50%, 66.8% in the three categories. The commonly prescribed drugs in all the three categories were ampicillin, gentamicin, amikacin, cefotaxim, co-trimoxazole, metronidazole, lactobacillus, acidophilus and I.V fluids. The average cost of therapy was found to be Rs.187.77 in the first category, Rs.386.66 in the second category, and Rs.649.5 in the third category. The percentage of amount spent on I.V fluids was found to be 40%, 45%, and 32 % of the total cost in each category. The percentage of amount spent on antimicrobial therapy was found to be 47%, 42.27%, and 63.29 % of the total cost in each category. From the results of this study, it was observed that antimicrobials are being used irrationally, which in turn increase the cost of therapy and the incidence of antimicrobial resistance. The adequate use of ORS should be encouraged so that the I.V fluid supplementation can be minimized. The usage of lactobacillus in the treatment of diarrhea should be reassessed. An education intervention study is in progress to enforce rational prescribing and promote rational drug therapy.

I9 Drug prescription trends in private hospitals - deviation from who's model list of essential medicines

Palaskar G.S.[1]*, Ghaisas M.M[1], Limaye R.P.[2], Zambad S.P.[1], Deshpande A.D.[1]

1. Padmashree Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune 411 018.
2. Dept. of Pharmacology, Rural Medical College, PMT, Loni, Ahmednagar.

A survey on the drug OPD prescribing pattern and use of drugs at private hospitals in Aurangabad district (M.S.) conducted. A total of 1550 OPD prescriptions were analyzed. The prescribed drugs were categorized and the prescriptions were analysed for number of drugs per prescription, fixed dose combinations, use of discarded drugs, ration of generic to brand drugs, percentage of drugs prescribed as per the WHO's model list of essential medicines (April 2003).

It was found that, the 1550 prescriptions contained 3030 drugs and the most commonly prescribed group of drugs were anti anxiety (12.31%) followed by antibiotics (1.41%); GI agents (9.08%); NSAIDs (8.84%); H_2 receptor antagonist (8.71%); CVS drugs (8.12%), multi vitamins (3.76%). The average number of drugs per prescription is 1.95. The use of fixed dose combinations is 6.23%. Percentage of use of discarded drug is 2.47%. Percentage of use of injectables is 1.95%. Only 10 drugs (0.03%) were found prescribed by generic name. The percentage of drugs prescribed as per WHO's model list of essential medicines is only 12.84% which include anti anxiety (0.06%), antibiotics (3.2%), GI agents (3.4%), NSAIDs (0.92%); H_2 receptor antagonist (3.3%), CVS drugs (3.13%), multivitamins (3.76%).

The present study indicates the high use of anti anxiety drugs on OPD basis, nearly equal to the use of antibiotics. It is advisable to restrict to WHO's model list of essential medicines for the advantages of cost effectiveness, high safety profiles and established efficacy, in OPD prescriptions.

I10 A pharmacoeconomic analysis of rheumatoid arthritis in a public hospital setting

***Sukhpreet[1a], Tiwari P[1b], Agarwal Vikas[2]**

1. Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, S.A.S. Nagar, Punjab
2. Department of Medicine, Government Medical College & Hospital, Chandigarh

The need for pharmacoeconomic studies is gradually becoming important when the costs and stakes of therapy are high in particular group of chronic diseases for example, Rheumatoid Arthritis (RA).

This study aimed at determination of the costs (direct and indirect) of drug treatment in patients suffering from chronic rheumatoid arthritis (RA) and also the determination of the costs of management of gastrointestinal side effects of Non Steroidal Anti-inflammatory drugs (NSAIDs).

For calculating the total cost of therapy, the original prescription of the patient was used. The study was done in a clinical setting with help of physician. Forty-two patients suffering from RA were included in the study. The direct cost of treatment included a) ambulatory costs (which includes visit to the hospital and the laboratory tests required), b) prescription cost (includes costs for RA drugs prescribed and used). The indirect costs included the cost of travel to the hospital, loss of work of patient, cost of household servant - if required - and loss of work of the accompanying person. The cost of additional drug(s) required to manage the side effects of NSAIDS was also calculated from the prescription.

The results of the present study revealed that total approximate cost of RA was Rs. 1001 (average cost) on a monthly basis. The indirect cost was approximately the double in case of patients who had an employment (only 3 out of 42; 7%) or in a case when the care taker was an employed person and not the patient. At times, the patient required household help to do daily activities or patient comes from a far off place to hospital and it leads to an increment in the indirect costs. The proportion of females in this study was 81% and of these almost half of them were postmenopausal patients. These results point to the fact that RA is almost equally prevalent in pre- and postmenopausal women.

The contribution of the costs of analgesics in total therapy cost was approximately over 20%. Since most of patients were prescribed with COX-2 inhibitors, the need for using PPI and H2 receptor antagonists was relatively low (only 10% pf the total patients) as compared with prescription of COX-1 inhibitors in RA. These costs were found to be approximately 10% of the prescriptions' direct cost.

I11 Prescribing errors and the impact of clinical pharmacists intervention in department of dermatology

Lakshmi Priya[1], Rexy J[1],Iman Rabia[1], and Vasantha Janardhan[1]

[1]Sri Ramachandra College of Pharmacy, Sri Ramachandra Medical College and Research Institute (Deemed University), Porur, Chennai 600 116.

The role of responsibilities of pharmacists have changed tremendously due to expansion in Research and Development, Drug/Poison Information Services, Prescription Monitoring, etc. The present study involves the assessment of prescribing errors by clinical pharmacists intervention in the Department of Dermatology.

The study was conducted at Sri Ramachandra Medical College and Research Institute (Deemed University), Porur, Chennai. The study was conducted for a period of 2 months between July – August 2003 and 218 patients were included in the study during this period. Among them 181 were 'Out-Patients' (OP) and 37 were 'In-patients' (IP). On OP basis the female population fairly exceeded the male population and IP analysis revealed that male population slightly predominated the female population. Patients between the age group of 11-80years were included in the study and the most frequent age for intervention was endowed between 11-50 years of age.

The interventions were reported separately as IP cases and OP cases. 24.3% (44) of the OP cases and 73.0% (27) of the IP cases were intervened. A total of 166 interventions have been made out of which 82 were OP intervention and 84 were IP interventions.

A significant number of clinical pharmacist interventions were made to improve the prescription trends and patient care, which was warmly welcomed by the physicians and postgraduates of the department of dermatology.

I12 Prescription monitoring for anti-hypertensive drugs in punjab university health centre

Anil Kumar*, Tiwari H.K. and S.K. Kulkarni

BH-151 (East), Shalimar Bagh, Delhi 110 088

Present pilot study was conducted in order to establish drug-prescribing trend of antihypertensive agents at Panjab University Health Centre.

The pilot study of six-month (Sept to Feb) duration was conducted at Panjab University Health Centre and information's were collected from the patients attending the out–patient-department through a chance random sample method. WHO based prescription-auditing performa was used for data collection.

Study revealed that most of the male patients were on monotherapy (60%) whereas combination therapy was majorly prescribed among female patients. Among the monotherapy category, four classes of drugs were used: calcium channel blockers (48.08%), β-blockers (46.15%), ACE inhibitors (3.85%) and diuretics (1.92%). Among monotherapy, calcium channel blockers were majorly prescribed whereas diuretics were least used. Among those who were treated with drug combinations, 92.1% received two drugs and 7.9% received three drugs regimen. In combination therapy, two-drug combination (beta blocker + calcium channel blockers) was majorly given to the patients. Overall 57.78% patients were treated with a single anti-hypertensive drug and 42.22% were treated with antihypertensive drug combinations.

The present study represented the current prescribing trend for anti hypertensive agents and highlighted the certain shortcomings in the existing prescribing practice. Study concluded that there was a considerable scope of improvement in the present prescribing pattern of antihypertensive drugs to improve the patient health further.

I_{13} Patient Counseling: India v/s U.S.A.

Jaisha J.*, Zaina P.Q., Manjari G., Poddar S.S.

Principal K.M. Kundnani College of Pharmacy, 47 R.G. Thadani Marg, Worli Sea Face, Mumbai - 18

'Patient counseling' as reported is not being implemented in the Indian scenario. Thus the main objective of our study was to understand the prevailing status of patient counseling being practised in India and the USA and account for the differences seen.

A comparative study of patient counseling system adopted in India and the USA was done. Information regarding the status in USA was procured by corresponding with practising pharmacists via internet which showed the effective implementation of patient counseling in USA. Verbal and written information was given to patients in an enclosed area to maintain privacy and long term patient care was administered. The status in India was obtained by surveying doctors, chemists and pharmacists. Firsthand information was obtained via questionnaires and interviews.

Results of the study and survey were critically examined and quantified using suitable statistical techniques. 60% doctors regretted that patient counseling was not observed in India. 30% doctors said that pharmacists should be given a chance while 70% stated that pharmacists were incompetent for the said job and patients lacked trust in pharmacists.100% chemists said that they didn't offer information unless asked, as their sources of drug information were not standard. 90% pharmacists said that they weren't given the opportunity to practice patient counseling and 70% pointed out their incompetence due to lack of training.

The experiment suggested the following solutions:

1. Effective implementation of the law which says that a registered pharmacist should be present at the chemist shop at all working hours.
2. Encourage pharmacists to believe in themselves as true professionals and to partake in patient counseling as well as the rest of their duties.
3. Better harmonization of the medical and pharmaceutical fraternity to ensure smooth functioning of the health care system.
4. Enhancing the computer softwares to use as aid to the pharmacist in counseling.
5. Providing specialization for B.pharm freshers who feel that their training was inadequate for counseling.

I_{14} Mifepristone-misoprostol in early first trimester abortion: interms of success, side effects and acceptability

A.Mohathasim Billah*, R.Manavalan, S.Viswanathan

Gautham College of Pharmacy, RT Nagar, Sultan Palya, Bangalore 560 032

Medical Abortion is a revolutionary addition to women's health care. Medical abortion is a safe and effective alternative to surgical abortion. In our study, mifepristone in combination with misoprostol for the termination of early pregnancy with gestational age = 63 days is effective in 97.40% of women. Only 3.6% of women who under went medical abortion treatment had incomplete abortion and that was made complete by surgical method. Four types of dosage regimen were adopted in our clinical study, viz. 600 mg of mifepristone and 400 mcg of misoprostol shown 93.43% of success rate, the another regimen 200 mg of mifepristone and 400 mcg of misoprostol showing 100% of success rate. The remaining dosage regimen that is 400 mg of mifepristone and 400 mcg of misoprostol had shown 83.36% and 200 mg of mifepristone and 800 mcg of misoprostol had shown 60% of success rate. All these dosage regimen were well tolerated with minimum side effects. The study showed a good result in primi gravida (first pregnancy) and multigravida (more than one but less than three) and the chance decreases in grand multi gravida (more

than three). With the gestational age of the foetus taken into consideration there was over 90% success rate of medical abortion in cases with foetus of less than 46 days or more than 50 days of gestation period, and the foetus in the range of 46 to 50 days gestation gave only 84.6% success rate of medical abortion. In considering the age of the women the success rate was 100% in 15 to 25 years of age and it was a little reduced (83.3%) for cases of 26 to 35 years of age. The success rate kept declining for those patients who had a history of previous abortion done.

I_{15} A study on water borne diseases among school children, found in slum pockets of sambalpur municipality area, Orissa

S.N. DAS[1], P. K. PANDA[2], P. SUNITA[3]

U.D.P.S. Utkal University, Bhubaneswar

Water borne diseases are the common diseases in the slum areas of Sambalpur Municipality due to deterioration in the quality of water, day by day due to urbanization, industrialization and over utilization and misuse of water. River Mahanadi is the source of drinking water but agricultural waste, industrial waste, domestic drains & hospital garbage's are polluting this water source. The people who are using this river water are seriously suffering from water-borne diseases like gastroenteritis, Bacillary dysentery, Amoebic dysentery, Typhoid fever, acute dirarrhoeal diseases and viral hepatitis (jaundice).

A total 602 nos of school children were registered for water borne diseases at Sambalpur head quarter hospital. The total number of slum children 395. Out of total 602 school children, the 325 (slum children) were affected by the water borne diseases. Most of slum children suffered from bacillary dysentery 170 (43.0%), amoebic dysentery 118 (30%), ascariasis 13 (3.3%), hookworm infection 4 (1.0%), and gastroenteritis 20(5%), where as only 70 children were free from water borne diseases. From this survey, it is indicated that most of slum children from 8 years of age to 13 years of age suffered from bacillary and amoebic dysentery. 5 years of age to 7 years of age slum children suffered from ascariasis, and hookworm infection.

I_{16} Cardio detect - a new generation of lab independent cardiac infarction test

Urvi Doshi*, Zarna Pandya, S.S. Poddar

K.M. Kundnani College of Pharmacy, 47, R.G. Thadani Marg, Worli Sea Face, Mumbai - 18.

Around the world, about 25-30% of people die due to myocardial infarction every ear. Early diagnosis is such cases, decreases the extent of damage to myocardium and facilitates, early and specific treatment. Therefore, such tests are in demand. CardioDetect is world's fasted lab independent cardiac infarction test. The objective of this study was to understand its basic principle and mechanism of working and to determine its advantages over other such existing tests in the market.

The experimental work was done by refering to text and interviews with personnel's involved with development and use of this product.

The study indicated that, since an early diagnosis in myocardial infarction increases the chances of patients' survival, such tests are in demand. Cardio Detect is world's fastest cardiac infarction test. It measures myocardial protein hFABP and gives reliable results 35 minutes after the onset of symptoms. Its compact design facilitates transport and immediate availability. It is very useful in emergency units, rescue units, airlines, etc.

Considering the need of the hour for a faster marker for detection of myocardial infarction cardio detect has a promising future. However, its cost factor in comparison to other such products available in market raises doubts about its use in poor and developing countries like India.

I_{17} Paediatric nephrology and drug usage in a multispeciality tertiary care teaching hospital

***Divya P.T., K.G. Revi Kumar, G.P. Mohantha R. Veena**

Kuzhiyalummoodu House, Kumarapuram Medical College, Tiruvananthapuram 695 011, Kerala

Pharmaceutical care implies all pharmacy activities aimed at promoting right use of medicines by the patients in the right manner.

It is of great use to special groups of population like the elderly, mothers, children and the chronically-ill; especially when the patient is a child and presents with renal impairment or chronic illness.

The treatment of primary glomerular diseases remains controversial and largely unsatisfactory, where Drug Usage Evaluation (DUE) has its significant role.

The present work was carried out at Thiruvananthapuram Medical College hospital, in Paediatric Nephrology unit, during July to November 2002.

The study shows that:

Average number of drugs prescribed per day for a patient = 5.72

Average number of drugs prescribed under generic name =1.4

Average number of parenterals prescribed per day for a patient = 3.56

Percentage of patients receiving parenteral therapy = 71.3%

Penicillins were the major group of antibiotics prescribed, followed by cephalosporins, Analysis showed that 55% of the patients were prescribed Penicillin-V, 39% with crystalline penicillin at the same time 29% of the patients received cefotaxim.

Some of the drug interactions identified, of major clinical significance include Prednisolone with diuretics, Ranitidine with antacids, Ranitidine with Nifidipine, salbutamol with diuretics, Gentamycin with Pencillins, Enalapril with Antacids, Spiranolactone with ACEI and Phenobarbitone with Acetaminophen.

The clinical pharmacist can apply their clinical pharmacy skill and knowledge of applied pharmacokinetics to ensure that the treatment is appropriate and offer the patient maximal efficiency and minimum toxicity.

I_{18} Unjudicial division of sustained release tablets for therapy

Dolly Talreja*, Chivate A., Poddar S.S.

K.M. Kundnani, College of Pharmacy, 47, R.G. Thadani Marg, Worli Sea Face, Mumbai - 18

Sustained release systems include any drug delivery design that achieves slow release of drug over an extended period of time. In either of the sustained release designs ie reservoir devices, matrix devices, breaking / subdividing of tablet before administration to the patient is not advisable. The results would be disastrous in coated tablets, noticeable in matrix tablets.

This work was aimed at studying the highly relevant problem ie administration of sustained release tablets by the patients after breaking into half or one fourth. After careful screening it was decided to evaluate status of such administration pattern of marketed Nifedipine sustained release tablets.

For the purpose of data acquisition market research was done aiming at information regarding the tablets with & without score marks. A survey was conducted regarding the administration patterns of Nifedipine sustained release tablets & awareness about such a practice regarding sustained release tablets & its effects. The next step was dissolution testing of marketed Nifedipine sustained release tablets (whole, half, 1/4 th tablet) as per USP. Also the B.P of patients on such a therapy was monitored for a fixed period of time under supervision of a medicinal practitioner.

Market research showed that out of 10 brands studied,3 were found to be having score marks. The survey proved existence of lack of awareness about such effects among 10% practitioners & 90% patients. Clinical studies proved administration of divided tablets lead to loss of sustained release property & inadequate therapeutic action, which was supported by dissolution profile of half&1/4 th tablets showing higher immediate release of drug as opposed to whole tablet with sustained release.

The study was successful at proving that practice of breaking sustained release tablets before administration existed & was harmful to the patient population.

I_{19} Therapeutic budget modeling: An accurate road to budgetary allocations in the public health care setting

George K John*, Martie S Lubbe* and Jan HP Serfontein*

*Pharmacy Practice, School of Pharmacy, Faculty of Health Sciences, Potchefstroom University, Potchefstroom, South Africa.

In South Africa in the health sector, 80% of the countries population are dependent on the public health care sector for their health care needs. The primary health care structure was established as a solution to the above, with the view of providing a level of basic care for all. The objective of the study was to analyse the cost related perspectives for the formulation of a therapeutic budget model, for use as a planning and control instrument in the usage of medicines at a primary care level in the public sector. Data utilised in this study were obtained from patient records of six local authorities primary health care clinics [N=1313] in Potchefstroom over a 24-day period.

The average cost of medicines per consultation was R7.02 ± 9.52 [N=R19645.38] for all medicines (including diagnosis for which medicines was not supplied) and R 8.25 = 10.97 [N=R13672.86] excluding anti-mycobacterials. Due to the nature of treatment of tuberculosis by the DOT system the prevalence and average cost of anti-mycobacterials were separately analysed.

The average cost per medicine item was R 4.19 ± 3.85 [N=4686] for all medicines [N=R19645.38] and R4.59 ± 5.33 [N=2978] excluding anti-mycobacterials [N=R13672.86]. The budget and pharmacological groups which were having an average cost of treatment and prevalence of≥10% constituted 70.79% and 43.62% of the total medicines used (excluding anti-mycobacterials) [N=2978] and 71.33% and 31.88% of the cost [N=R13672.86], respectively, of medicines issued to patients in the clinics.

From the study it was projected that for all the six clinics in Potchefstroom a amount of R2, 471,488.80 was needed for optimal functioning and management of the clinics. This amount was 262.78% more than the actual annual budget allocation of R1, 183,732.00, in variance.

It is thus foreseen that the compiling of a therapeutic budget modeling system can significantly help the public sector to prepare and plan budgetary policies for better formulary and resource management, as the preliminary reports are promising.

J1 Use of microwave technology in chemistry practicals - Part II: synthesis of organic compounds

Shrishailappa Badami, Choksi Rakshit K*., Saravanan R. Sunil V. Sharma and Suresh B.

Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Rocklands, Ootacamund - 643 001 (TN)

Microwave induced organic reaction enhancement (MORE) is a simple, clean, fast, efficient and economic method for the synthesis of organic molecules and has emerged as a tool towards green chemistry. With an objective to develop newer methods for rapid and eco-friendly synthesis and to introduce principles of green chemistry in chemistry curriculum, the present work was carried out. Synthesis of several organic molecules, which are common in organic chemistry practical, was conducted using microwave technology. Higher yields were achieved for the preparation of benzil, benzopinacol, benzoic acid, benzylthiouronium chloride, iodoform, benzillic acid and succinic anhydride by following microwave methods in lesser duration when compared with the conventional procedures. The preparation of benzil and benzopinacol by conventional heating required 2 hours duration to get 91 to 30% yields, respectively. The same reaction under microwave irradiation of 5 and 8 min. produced 98.4 and 44.1% yields, respectively. Benzoic acid, benzylthiouronium chloride, succinic anhydride, iodoform and benzillic acid preparation consumed 60, 30, 20, 15, and 15 15 min. duration conventionally to get 62.8, 87.1, 89.2, 31.2 and 68.9% yields respectively. Under microwave assistance, these reactions consumed 3,4.5, 9, 4 and 1 min. to produce 69.0, 93.7, 100.0, 41.2 and 76.8% yields, respectively. The new procedures developed can be used for routine chemistry practical at undergraduate and postgraduate levels and can serve well in effective teaching of synthetic chemistry.

J2 Effective method of teaching for professional education

Samanta M. K.*, Atul Daroi and Suresh B.

Dept of Pharmaceutics, J.S.S. College of Pharmacy, Elkhill Road, Ootacamund 643001.

Teaching profession has become the largest profession and it is a highly respected and noblest profession in the world. A profession is an occupation based on specific theories of knowledge and skill development, having a provision for systematic training and a type of licensing. Every professional person has a body of verified experiences. Teaching is not carried out through a teacher only. Besides teacher, a number of persons – parents, community Gurus, television, radio programmes, etc. also take part direct or indirect manner.

Teaching should be regarded as a profession. It is a form of public service which requires of teacher expert knowledge and specialized skills, acquired and maintained through rigorous and continuing study, it calls also for sense of personal and corporate responsibility for the education and we of the pupils in their charge.

This attempt to formulate a synopsis of how best the available resources in an institution can be utilized most effectively for better teaching and better understanding of students. It indicates the proper planning and execution of lectures with available resources to their maximum efficiency and also the assessment of students, so that we can produce a moral as well as brilliant student generation which leads to build a developed India.

J3 Microscale experiments - An emerging trend in chemistry

K. R. Bhavsar*, P.U. Patel, C.N. Patel, M.B. Patel, J.R. Patel, F.A. Mehta

Dept. of Pharma Chem., Shree S. K. Patel College of Pharma. Edu. & Research, Ganpat Vidyanagar, Kherva, Dist: Mehsana, Gujarat 382711

Reduction of chemical use to the minimum level at which experiments can be effectively performed is known as Microscale Chemistry.

Microscale chemistry is an environmentally safe pollution preventing method of performing chemical processes using small quantities of chemicals without compromising the quality and standard of chemical applications in education and industry.

Microscale technique was first developed at the Dreyfus/ Woodrow Wilson summer institute during the summer, 1987. Several years later a CD Rom was developed called 'small scale' and based upon 80 small-scale experiments.

Micro scale experiments are also termed as the Nanotechnology. "Nano" derives from the Greek word for dwarf; it means a billionth of that unit. That means that the experiments, are performed on Nano scale. The emerging field of nano science & nanoengineering are leading to unprecedented understanding & control over the fundamental building blocks of all physical things. Nanotechnology is the way of ingeniously controlling the building of small & large structures, with intricate properties, it is the way of future, a way of precise, controlled building, with incidentally environmental benignness built in by design.

With microscale experimental technology, the amount of a particular chemical needed for an

experiment may also be reduced. Major improvement can be affected in the chemistry laboratories by the use of this technology because the amount of solvents, reagents or chemicals used would be very less which would consequently result in improving the atmosphere of the laboratories. In addition, since the quantity of reagents is less, the time taken for reactions, washing and cleaning of glassware is also less. Owing to their small size the space taken up by the glassware is also less, reducing the cluster in the laboratories.

J_4 Computer aided drug design - is it a milestone or just a corner stone in drug discovery

Geeta Gwalani*, Vinita Katara, Amita Mirani, S.S. Poddar

K.M. Kundnani, College of Pharmacy, 47, R.G. Thadani Marg, Worli Sea Face, Mumbai - 18

On an average it takes 8-12 years and more than US $ 360 million to bring a new drug to market with clinical trials accounting for approximately one-half of the time and one-third of the cost required. Yet upto 50% of these trials fail to provide conclusive or useful results. The old approaches have been supplemented by sophisticated new techniques that can screen more compounds in an hour than an army of technicians can screen in a month. High speed computers that utilizes the classical principal of structural variation and pharmacological observations is frequently a visually attractive technique based on colourful and complex computer images.

The objective of this study was directed towards the advancements in the field of drug discovery. "Does CADD have the potential to bring about a revolutionary change in the drug development program"? was a pivotal question that we want to put forth through this work. Thereby indicate the advantages and disadvantages that CADD can offer in comparison with traditional method of Drug Discover. Various opinions expressed by experts in pharmacy professionals, computer professionals and software engineers were considered and evaluated. A survey was carried out for collections of facts and ground realities suggesting the current status of CADD.

To conclude the central theme of drug discovery is a search process in a short cut way which is being aided by computer from various directions, however CADD can be estimated as the best educative guess in drug discovery process while medicinal chemists intuition is the ultimate guide and computer remains as an intuition amplifier in drug discovery process.

J_5 Atom economy – A novel approach in synthetic/ medicinal chemistry

Mahesh, R.* & Venkatesha Perumal, R.

Pharmacy Group, Birla Institute of Technology & Science, Pilani-333 031. Rajasthan.

Atom economy or atom utilization means, maximizing the incorporation of material from the starting materials or reagents into the final product. The concept of atom economy/utilization is consideration of "how much of the reactants end up in the final product." It is essentially pollution prevention at the molecular level. Chemists should not only strive to develop reactions that produce high yields, but also these same reactions must aim for incorporation of all the atoms of the reactants into the desired products, thus eliminating the production of unwanted byproducts.

When we look at some common organic reactions (viz., rearrangement, addition, substitution and elimination reactions), we will find that some of these reactions are inherently more atom-economical than others. The rearrangement and addition reactions tend to be the most atom-economical followed by the substitution and elimination reactions.

Percentage atom economy is calculated by dividing the molecular weight of desired product by the molecular weights of all the reactants, products and byproducts generated in a reaction and multiplied by 100.

The importance of atom economy can be clearly understood by taking the example of synthesis of Ibuprofen by Boots Company and BHC Company. Both companies used the same starting material, Isobutylbenzene, but BHC Company achieved the target molecule, Ibuprofen, in 3 steps, whereas Boots Company in 6 steps. Due to eliminating unwanted byproducts BHC company achieved the % atom economy of 77% while Boots company achieved % atom economy of only 40% thus reducing the cost and being benign to the environment.

Atom economy plays a vital role in Green Chemistry, which is not only economical in industry but also it dramatically reduces the environmental pollution by incorporating most of the reactant material into the product. It is essential to teach the importance of atom economy to tomorrow's chemists to attain "Greener Environment."

J_6 Role of bioinformatics in pharmaceutical industry

K.Ramkumar*, M.Sangeetha*

Dept. of Pharmacology, K.M. College of Pharmacy, Melur Main Road, Uthangudi, Madurai 625 107, Tamilnadu

Bioinformatics is the hottest topic today in pharmaceutical R&D. Bioinformatics is the combination of biology and information technology. It deals with computer based analysis of large biological data sets. The Bioinformatics in R&D Process enables identification and development of new drugs. Genomics, proteomics, Combinatorial chemistry and HTS (High-throughput screening) have all contributed to a massive increase in the amount of data generated by the pharmaceutical industry. Bioinformatics helps in target identification, validation of drug response patterns, prediction of drug/target interactions, thus leading to a rational drug design. As the pharmaceutical industry is dealing with greater volumes of complex and inter-related data, the need for integration in the management of Bioinformatics data is growing more than ever. Pharma companies who are going for collaborative research with the major distribution information centres are to be linked by network. In life sciences cost-effective ways to integrate and manage large complex applications and databases need to be found urgently. Bioinformatics gives the world the answer to affordable medical treatment and fast diagnosis.

J_7 Students' perception on commercial approach of pharmaceutical education

Manish Narula*, N.M. Patel, B.K. Patel, P.B. Shah, I.M. Anand, B.G. Chaudhari

Shri B.M. Shah College of Pharmacy, Modasa - 383315

Formative and summative assessment of student learning is an essential component of Pharmacy education, to optimize the students thinking process in concern to commercial options available after graduate level pharmacy study, a survey is conducted in all (four) Pharmacy Colleges affiliated to North Gujarat University. Final year students who are in verge to enter in various fields are taken as subject of perception & their responses are analysed on statistical basis by normal proportion test. After applying a statistical to perception's received from final year students of Norht Gujarat University, its found that a awareness of commercial options available after B-Pharm is comparatively less, before students takes admission. On lying comparative approach students are more diverted towards academics and opt for further studies. Going abroad is also a choice for one third of students. As per students' perception developed after three years of Pharmacy education. B-Pharm curriculum is more diverted towards production-chemical & formulation compared to Pharmacy practice, for recent developments, students are moderately updated for most of them Pharm periodicals & journals are major sources of information.

From survey its reflects that future will be of knowledge based & possibility of commercial option available to graduates will shift to masters level.

J_8 Need of online pharma education in pharmacy colleges

Kuldeep Khandelwal*, Vijender S. Shekhawat, R.K. Nema, Santosh Gupta, Dheeraj Gupta, Sudhir Bhardwaj

Subhash Nagar, Udaipur, Rajasthan

Pharmacy Education aims to provide a forum for communication between academic teachers and practitioners, with an emphasis on new and established teaching and learning methods new curriculum and syllabus directions guidance. On structuring courses and assessing achievement as well as the dissemination of new ideas. The online pharmaceutical journal also recognizes the importance of policy issues and current trends in the context of education and professional development. The online pharmaceutical journal publishes reports of research and innovation in all aspects of pharmacy education and training, case studies, essays and opinions for comment, innovations in laboratory practice, reviews and reports on information technology in education and reviews of current literature.

The Pharmacy Choice Web portal provides pharmacists and technicians with the most comprehensive suite of Web tools available, including career services, drug information, continuing education, Internet access and pharmacy-specific e-mail accounts. In addition to providing access to one of the only online courses for pharmacy technician training, Pharmacy Choice offers timesaving applications and helpful industry resources to pharmacists, pharmacy technicians and their employers.

The Journal of Pharmacy Teaching is a specialized medium of communication designed for educators at all levels within the field of pharmacy. The journal caters to those in the field who are engaged in the practice or research of education; particularly those who need to keep up with the advances in educational principles and strategies. It is a valuable resource for academicians at all levels, pharmacists who educate students and patients, graduate students considering academia, and those who train sales personnel to interact with pharmacists and other health care professionals.

Save Time, Learn Online

J_9 Pharmacy education: current problems and suggested solution

S. P. Vishnoi[1], B.P.Nagori[1] and T. Jha[2]

1. L. M.College of Science and Technology (Pharmacy), Jodhpur 342003 (Rajasthan)
2. Natural Science Laboratory, Division of Medicinal and Pharmaceutical Chemistry,

Department of Pharmaceutical Technology, Post Box No.-17020, Jadavpur University, Kolkata-700032 India.

World is witnessing a remarkable change in present pharmaceutical scenario with the introduction of information technology. It was concluded that Indian pharmacy institution, Universities need to introduce a variety of new courses to enable students to equip themselves with the specialized skills that will be demanded of them in the near future. This will ensure that they possess the ability to complete on a global level. We in India have yet to begin. In 1970, Prof. M L Shroff, father of Pharmacy Education in India, wrote that Indian pharmacists would soon shift focus from a product-oriented to a patient-oriented approach. Unfortunately, 30 years after these statements, we continue to disappoint the visions of Prof. Shroff. We have failed terribly to take heed of his words, or for that matter, to provide proper health care delivery to our patients.

In present condition the pharmacist has no social status and much importance. Day by day the newer technology are developing and comparatively the pharmaceutical education is not upgraded up to a level. So there should be modification in pharmaceutical to bring the integrity of education through the country for developing future pharmacist steps should be taken for strengthening or improving the basic organization of pharmacy in India.

While the pharmacy professional associations push the blame on the trade bodies for not wanting to professionalise, nobody is ready to take the blame as to why we do not have sufficient pharmacists in the country, why there are very few community pharmacists who are professional, why are new pharmacies given licences if we claim that we do not have enough pharmacists in the country to man our retail outlets, why is the condition of some of our retail outlets pathetic when we talk of professionalism and advancement, why cannot we achieve excellence in our teaching institutions, why are we dilly-dallying to start continuing education programmes .Before we lift the gun and shoot squarely at trade associations, we have a lot of questions to answer ourselves.

J_{10} Promoting entrepreneurship

Udichi Kataria* & G.D. Gupta

B.N. College of Pharmacy, Udaipur - 313 002 (Raj.).

The mushrooming up of pharmacy colleges in every nook and corner of the country, has been deteriorating the equality standards of pharmacy education, and will create considerable unemployment of pharmaceutical manpower after four years. Under the circumstance, where the chances of wage - employment for pharmacy pass-outs are meager with the increase in number of candidates for the limited number of jobs, promoting entrepreneurial avenues amongst the students may be a viable alternative leading to their self-employment.

Some of these competencies mentioned in the curriculum required to be implemented in various states are communication, interpretation and managerial skills, effective interpersonal relations, knowledge of running a factory and accomplishing a project etc. Based on their competency profiles, many opportunities are lying ahead of the pharmacy students, which include jobs like production and quality control manager, medical shops, surveyors, medical representatives, dieticians, research and development projects, establishing new drug manufacturing factories etc.

Promoting this entrepreneurial awareness is essentially the need of the hour. Various attributes for successfully running an enterprise can be briefed to the students. A few of these attributes are high need for achievement and power, independence and sense of efficacy, propensity to take risk, team spirit and problem solving attitude, communication, negotiation and interpersonal skills, critical evaluation and farsightedness etc. Students should be properly identified and motivated for developing and nurturing of these appropriate entrepreneurial skills.

It was found that it is the right time to establish a network of professionalism linked with a drive towards entreprenuership. Once such initiatives are taken, success stories will be created for diverting sizable number of students towards effective and best possible employment avenues.

J_{11} Economization of pharmacy practices

Udichi Kataria*, Rahul Garg, Jayesh Dwivedi, Amit Jain & G.D.Gupta

B. N. College of Pharmacy, Udaipur –313 002 (Raj.)

Pharmaceutical education plays a very prominent role in attaining sustainable and equitable development of a country. Under the present norms and standards set for Institutional functioning and the fee structure, there is an urgent need to make the education cost effective i.e. within the reach of the common man Cost, quality and time go hand in hand. Cost is enhanced with the time while quality is the part of process. In the present scenario, it is essential to adopt some of the cost reduction tools and techniques in technical education. Quality is based on the following parameters like – Equipments, Infrastructure, Faculty, Methods, Management, R & D, etc.

Cost is reduced with quality applying following tools i.e. Development of import substitution for materials, Using Modern Technology, Optimizing inventory, Multiply use of space, Communication evils, Promoting in-house R & D techniques, Analysis of wastage, etc

Today's society is knowledge based, which should possess the following dimensions like efficient education sector (economic sector), better professional / technical classes (occupational distribution), innovative knowledge (axial principle), control technology and assessment (future orientation) and intellectual technology (decision making).

In the present study some suggestions and practical applications are incorporated to justify the cost-effective education like flexibility in curricular design, IT based education technology, change in teaching norms and faculties, downsizing the Institutions, teachers re-designed as facilitators and integrators, sharing and optimization of generated resources and ploughing back of their share by the passed out students to their alma mater.

J12 Pharmacist's on bioterrorism, part - I

P.K. Mohapatra*, B.R. Panda, U.S. Mishra

Seemanta Institute of Pharmaceutical Sciences, Jharpokharia - 757086.

The use of biological agents as weapons of mass destruction is the main aim of bioterrorism. There are many biological agents which are used such purposes are classified into three categories based on their potential for production, impact on health and public perception. Most of the agents are mainly viruses. The main viruses used in bioterrorism are smallpox viruses, hemorrhagic fever viruses, influenza viruses etc.. There are only limited strategies for the early detection of viruses released as a bioterrorism event. Smallpox is the one of older infection. This virus is great threat as a bioweapon because it fatality rate in 30% or more in unvaccinated individuals. For preventing this infection safe antiviral therapies is the first line of choice. Cidofovir has broad antiviral activity against several DNA viruses, including orthopoxviruses etc.. Aerosolized or subcutaneous cidofovir given immediately before the aerosolized infection was effective in preventing illness and death. Vaccination is the best prevention for this infection. Hemorrhagic Fever viruses (HFV) are small lipid enveloped RNA viruses belonging to four taxonomic families. These include filoviruses, bunyaviruses, flaviviruses and arenaviruses. These viruses are great harm to population because they can be produced in large quantities and aerosols can infect humans. The only licensed vaccine is the 17D strain Yellow fever vaccine. Antiviral therapy for HFV infections is limited and usually effective against only a limited number of viruses. The inosine monophosphate inhibitor and ribavirin are widely used in these infections. Some other viruses might emerge as potential bioterrorism agents. Chief among these is influenza A because it possess significant virulence. Nipah virus, a recently described, deadly paramyxovirus, causes significant neurological and respiratory disease. Encouraging studies helps a greater understanding of these organisms and potential methods to protect humans from infection and to treat those with established infections.

J13 Networking of pharmacy shops

Abraham Thobias

No. 30, Malanganathapuram, Pallavaram
Chennai 600 043

In India the pharmacy shops are functioning like a provisional store and they are dispensing the medicines to the people without any standard norms and against any prescription from the qualified Physicians. If this trend continues the people will be taking the drugs without understanding the adverse effects and inducing the toxicity in their body to the maximum level. Because in number of shops they are dispensing even the scheduled drugs to the people by counter sale (OTC).

In provisional stores and vegetable shops the medicines like pain remover and anti-pyretic drugs are sold. The costs of these medicines are cheap and easily available to the patient hence they themselves come forward to purchase these medicines and in due course of time they become addict to these medicines. It will lead to the side effects like liver failure and kidney failure. Medical shop vendors act like professional vendors/Practicing Physicians and they themselves prescribe the medicines to the people by which act they are playing with the human lives.

To improve the quality of pharmacy shops and to overcome the patient compliance all the states should come forward to have the solution of Computerizing the pharmacy Shops and networking them to the Drug Controller of their state. To make the existing pharmacy shops a computerized pharmacy shops the cost will be below Rs 50,000 only. The State should come forward to network all the Pharmacy Shops in order to have a better control over the Pharmacy shops and to avoid the banned drug movement in the state.

Government should come forward to enact the necessary Acts or amend the existing Acts with suitable provisions to make it a legal procedure for computerizing the pharmacy shops. Through this legal procedure we will be able to connect all the pharmacy shops in a network under the Control of the Drug Controller. This networking center will function under the direct supervision of the drugs controller. Through this they can monitor all the pharmacy shops from one place. All the billing will be monitored by the sales tax officers so they need not keep the accountant for the shop, the auditors can audit the bills through net auditing.

The pharmacists can have the availability of drugs list in their fingertips. They can maintain the

purchase inventory, stock available and non moving drugs list. They can get new drugs information and new brands.

By computerizing the Pharmacy shops even a single tablet sale can be recorded in the billing. Through this we can prevent the unauthorized drug sale like sample sale and narcotic drugs sales. They will be able to know the availability of drugs from various whole sellers and they can have the comparative price list. For the unknown drugs they can get information from the drug information center. The price of the products can maintained uniformly in all the shops with sales tax instructions. Rural pharmacists can get the latest drug information as and when they are need of it. Expiry date of the drugs will be brought to the notice of the Pharmacists periodically by the system itself. Pharmacists can have the banned list of drugs in their fingertips.

Government Health Department can monitor the newly spreading disease through the drug sales by the sales report. The Public health department can have a vigil over of diseases spreading in a particular area. The public health department can try to make propaganda about the spreading disease in that area and make awareness among the people.

J14 B.Sc. and B.Pharm recruits in industry

Lipika Chablani*, Monica Chauhan, Ramchandra Patale, Prashant Mande, S. S. Poddar

K M Kundnani College of Pharmacy, 47, R.G. Thadani Marg, Worli, Mumbai 400 018

The work highlights the currently existing situation of B.Sc. and B.Pharm recruits in pharma industry providing improved insight to the issue.

Four sections were targeted for a close-ended objective type of direct interview in the area of Mumbai. n =10 professors were projected. Low and better salary[1] option by other faculty graduates was quoted as the reason for recruits as per 70% of them. n =50 pharmacy students. 84% said the hurdles are due[2] to professional enchroachments. 98% recommended for reserved posts in industry.

B.Sc. students, n =50, 40% were unaware of pharmacy profession. 50%[3] said they lacked the knowledge of pharma subject 50% were planning to join the industry!

Of n =5 of pharma industries questioned 100% were affirmative[4] for non-pharma graduate employment. 4 our of 5 agreed to good technical skills of pharma graduate. Work showed the increasing number of employment of other faculty graduates in pharma industry and availability of wide range of fresh graduates for industry to choose from.

It was concluded that the pahetic situation of pharma graduates is due to apathy of regulatory authorities exploitation by pharma industry, complacency in pharma graduates and adaptability of science graduates.

Thus before blaming any one we have to tighten our own belts to improve upon our lackings and also persuade government to case the situation by bringin in and implementing needed legislatures.

J15 Experiential teaching and learning: A need of new Era

Anita Sharma* Komal Balani, Madhu Gupta, Shikha Raheja, Sonu Verma. Anju Goyal

B.N. College of Pharmacy, Udaipur (Raj.) 313001

Winston Churchill said " I am always ready to learn, but do not always likes to be taught".

Education is the mile stone of modern society and therefore, re-evaluated whenever such need is sought. Upanishads mentioned three steps of teaching and learning namely "sravana" listening to utterance or texts, "Manana" deliberation or reflection on the topics thought and lastly "Nidhidyasana"- truth could be realised and attained.

In the modern competent world, where the expectations of society from pharmacists are always maximum, there is a need to follow the above principles with a little modification to satisfy today's need.

Experiential teaching and learning methods are the only solutions to this context.

Experiential teaching involves case based situational studies through which the student is actively involved and motivated to learn. The students are presented with a scanario, from which they have to identify the problem and decide what information has to be sought and who should do that.

Experiential learning techniques will facilitate more student-student and student-tutor interface resulting in professionals with much better skills than previous cohorts.

Active learning techniques could inculcate " want to learn" climate among student and the tutor is able to direct then in the right direction. Self-motivation and self-directed learning are key attributes of this teaching technique.

"Tell me and I forgets show me and I remember. Involve me and I understand" true in present context also and methods of experiential teaching and learning are effective way to attain this goal.

J16 Pharmaceutical research at educational institutions

Ajeet M. Godbole* and Fatima Sanjeri Dasankop

KLES's College of Pharmacy, Vidyanagar Hubli 580 031

There are many motives of doing research. Some are tempted by the excitement of discovery where in the researcher has a chance to add something new which helps in expanding frontiers of knowledge. For some who take research as te challenge these individuals really relish every step of work. Such scientists remain undeterred by drudgery, disappointment. For few others the main objectives are the pursuit of prestige or the need for publication.

Actual purpose of the research is

- ✓ A chance to study the subject in depth
- ✓ Development of the special skills
- ✓ Obtaining a higher degree
- ✓ Obtaining Patents
- ✓ Travels grants for presentation of papers at various national and international conferences and other amenities. But the purpose of the compulsory research
- ✓ Promotions

There is strong need to make research more exciting, fruitful and practised. In this research paper the authors highlight the actual need for the research. ***The research must be value based and not need based.*** The link between research and promotions must end immediately and genuine research work must be nurtured to grow and bring laurels to the institution and country as a whole.

J17 Pharmacist- A key person in disaster management

Page A. B.*[1], Tare M. S.[1], Baheti D.G.[1], Samb. A. A.[1], Wakhare J. B.[1], Kamalapurkar K. A.[2]

1. SCSSS College of Pharmacy, Shirur (Pune).
2. DSTSM's College of Pharmacy, Solapur.

A disaster – an event of nature or man made, that leads to sudden disruption of normal life of society, causing damage to the life and property to such an extent, that normal social and economic mechanisms available are inadequate to restore normalcy. Disaster evoke damage to the health – Physical, psychological, and social – as a chief area of concern. Some disasters like various epidemics can be brought under control by timely managing the necessities, while some other are to be managed after their occurrence, though some can be prevented. Being a health care team member, drug information specialist, and responsible citizen of community, Pharmacist is in unique position to handle such situations.

He may play a role in preventing and controlling the epidemics by educating people regarding cleanliness, maintenance of hygiene, supply of anti-infectives etc. in the community.

A pharmacist can play a very important role in handling situations arising from natural disasters, man made accidental disasters, bioterrorism etc. as...

1. First medical responders.
2. Drug information specialist.
3. Guide for disaster preparedness.
4. Help in psychological, physical counseling of affected.

J18 Pharmacy fights back terrorism

Tina H. Bhatia*, Arthi..B, Girish H., S. S. Poddar

K. M. Kundnani College of Pharmacy, Mumbai – 18.

This project attempts to promote pharmacist in the health care system as health care professionals and to possibly propagate the idea of "Pharmacy fights back Terrorism".

The data was obtained through responses, which were generated through scientifically designed surveys and interviews.

On examining the responses obtained, following results emerged: 98% of pharmacists practicing in US are aware of their role in emergency teams and 70% are already members of emergency teams.

Most of the India based pharmacists are not fully aware of the work being done and role they can play as member of the emergency team.

The doctors working in areas where terrorist attack has taken place stated that they would prefer to have quality assistance, like the one provided by the pharmacist.

Pharmacists in India stated that they would prefer to work with doctors but shoulder to shoulder. On surveying students of B. Pharm. 88% showed enthusiasm and apparently felt they would like to join Dmat.

Pharmacists need to work with local hospitals, public health departments etc., in planning local medical response for natural and man made disasters. All the institutions should include the training for preparedness of pharmacists against terrorist attack. It is of paramount importance that pharmacist receive education to understand better and respond to reparation from unconventional chemical and biological weapons.

K_1 Essential drugs consumption in selected areas of pune city maharashtra: a market research

S.B.Bhise [1], Hemant Devi [2], Abhijit D. Nalawade*[3], Rohit Barge [4]

1) Govt. College of Pharmacy, Aurangabad
2) AISSMS College of Pharmacy, Pune
3) Govt. College of Pharmacy, Karad 415124
4) Concept Phamaceuticals, Satara

The concept of Essential Drugs is very important for a country like India, whereas people suffer from lack of medicine, despite thousands of formulations thriving in market.

The present study is aimed at identifying essential drugs consumption in Pune city, Maharashtra for the month of June-2003. Data was collected prospectively from the 10 stockist directly after interviewing them during their business hours.

Analysis of records from 10 stockist revealed the following data: -

- Turnover of top five drug (costwise) Rs. 10,25,419.
- Turnover of top drugs (volumewise) Rs. 4,33,648.
- Top five drugs (costwise): - Insulin (51.9%), Atenolol (16.9%), Carbamazepine (15.2%), Erythromycin (7.9%) and Ciprofloxacin (7.8%).
- Top five drugs (volumewise): - Atenolol (40.17%), Betamethasone (8.4%), Ibuprofen (10.8%), Carbamazepine (36.0%) and Aluminium Hydroxide (4.4%).

Percentage consumption of Insulin and Atenolol is higher in cost and volume comparison respectively.

It may be concluded that the co-existence of Diabetes and Hypertension is being increasingly recognised in selected areas of Pune City.

K_2 Pharmacists in continuous food hygiene & sanitation awareness education (Cfhsae) – an important aid in the implementation of health policies in jharkhand

Biswatrish Sarkar*, K. Jayaram Kumar, S.P.Bhatnagar. Department of Pharmaceutical Sciences,**

BIT, Mesra, Ranchi 835 215

Health is a function, not only of medical care but also of the overall integrated development of society. The health status of a society is intimately related to its awareness towards food hygiene and sanitation as well as to its value systems.

Jharkhand is a state, highly dominated by tribal population. Despite of various health care schemes implemented by the Government, every year hundreds of people are dying out of malaria, tuberculosis, hepatitis-B, jaundice. Diahorrea, cholera and G.I.T disorders are common problems of the people.

With this genuine concern we carried out a survey among pharmacists, physicians and common masses of the state to find out the lacuna between Health Policies and its implementation, and come up with best strategic solutions.

Our survey revealed that 58% of the rural mass is unaware of the National Health Care Schemes. Overall 47% revealed that there is no systematic education programme running at their place. Over 89% emphasized on introducing a systematic awareness education programme at primary school education. To curb this menace at grass root level, we have come up with following strategic steps-

- Systematic education programme at primary school education.
- Formation of groups and systematically educating them.
- Periodic review of the progress.
- Awards & recognition of the best work.
- Seminars and guest lectures.

When CFHSAE was taken up by NSS cadets of B.I.T, Mesra among the local villagers they met with 78.2% success. This success is being magnified by active collaboration of the educational institutes and the health sectors with an aim of healthy and prosperous India.

K_3 Continuous health cognizance through clans - A bridge between national health care programs and people of jharkhand

K. Jayaram Kumar, S.P. Bhatnagar, Nishi Kumari*, Pratika Srivastav**

Department of Pharmaceutical Sciences, BIT, Mesra – 835 215, Ranchi, Jharkhand, India

The culture of community determines the health behaviour of the community and its individual members. In one-way or the other, health status of the population influences the development of nation. Though, the Government of India is doing at its best still the basic health services are not accessible to the many rural areas of Jharkhand. Historically, Jharkhand

has been a state where the native population comprises of more than 70% of tribals and their bewildering variation in their culture and socio-economic backgrounds. There is general agreement that health status of people of Jharkhand is poor because of widespread poverty, illiteracy, malnutrition, and poor maternal and child health care services. So, genuinely present health scenario of people of Jharkhand is due to ineffective coverage of National Health Care Programs.

So, with this genuine concern we took the task of surveying and coming up to best solution to rejuvenate and make best use of national health care programs in Jharkhand. Our survey covered various health professionals, urban, and rural people. Our survey revealed that 70-80% people felt the absence of mass awareness programs and lack of interacting factors which between people and National Health Care Programs. 80-90% of people felt that spreading of health education from clan to clan should be a part of National Health Care Programs (NHCPs).

Our survey revealed that the following steps have to be taken for better implementation of NHCPs with reference to the people of Jharkhand –

- Education of people about NHCPs through clans.
- Periodic interaction of various clans
- Regular workshops, seminars, and play inacting the importance of NHCPs.
- Award and recognition of best work.

This process was met with high rate of success at BIT, Mesra in its NSS program. It is time that all educational institutes should join hands and should have single voice for a full-fledged network of health services so that eventually the dream of healthy and prosperous India came true.

K_4 Assessment of role of media on self medication in paramedical students

K.N.Venkateswara Rao, K.Shalini*, Iman R. Ahmed

College of Pharmacy, SRMC and RI(DU), Porur, Chennai 600 116.

Self/Personal care be defined as the primary public health resource in the health care-system. It comprises of health activities and health related decision making of individuals, families, friends, colleagues and so on. A general improvement in people 's general knowledge, level of education, and socio-economic status forms the basis for self –care. The rapid development in media and related communication systems facilitated the easy access to information on drugs like they use, mode of administration, characteristics etc. The health care team comprises of many other allied health professionals apart from M.B.B.S. who are in constant touch and equally knowledgeable on the drugs characteristics and usage. A Study was conducted to know the extent of self medication among these health care professional training students,

- The influence of various media of communication, on self medication,
- The influence of others on self medication.
- The pattern of self care in various therapeutic segmentation.

through a structured questionnaire among the health care professional students.

The study reveals an interesting aspect which influences on decisions making of self medication . Even though the subjects are from health care students with 66% have undergone self medication in past two years. 36.66% agreed upon the influence of parents advice and have undergone for self medication. 81.66% reported as they have come across the advertisements through T.V media but over all media comprising print, radio, T.V failed to initiate the self –care among the students (8%).

The therapeutic category utilization drugs was high in Analgesics, Antipyretic segments (40-50%) followed by Anti-histamines, Anti-allergics (25-30%), Cough suppressants (10%) and Antacids (5%), surprisingly the Antibiotics, multivitamins were at low (1-5%).

The most widely consumed brands were found to be Metacin, Crocin(58.33%), Coldact (20%), Allegra (5%), Diazine and Gelucil (5%). 80% of the participants were access to internet facility . But only 3% were to browse the medicine related web sites (medindia.net, medversity.com)

In conclusion the study participants were from the medical university student, the results reveals that the pattern of self-medication is limited to the earlier reported segment only. The media (T.V) influence on self-medication is relatively nil on these participants as the parents are of decision makers on drug use. Similar kind of study can be extended to non-medical, paramedical students is in progress.

K_5 Evaluation of presence of steroids in nonprescription anti-inflammatory drugs dispensed in SHIRUR taluka.

Samb A. A., Gavde R. R., Mullya R. M, Page A. B*., Tare M. S., Baheti D. G.

SCSSS College of Pharmacy, Shirur (Pune)-412210.

Steroids possess a per-hydro cyclo-penteno phenanthrene ring as a nucleus. Steroids are present abundantly in nature. The human body is capable of synthesising steroids to limited extent. The body can

also destroy steroids to certain extent, large quantities are excreted in the sebum, in stools as coposteroids & in urine as sex hormones & traces of cholesterol.

Steroids of adrenals are classified from pharmacological point of view as Mineralocorticoids & glucocorticoids. These corticoids are widely used in therapeutics. They are used particularly for relief of pain as it has nonspecific anti-inflammatory action. A large population misuses steroids, not only for relief from pain but also used for improvement of performance particularly by athletes.

On long term use, these steroids produce severe adverse effects, like immunosupression, steroid induced hypertension, GI ulcers, behavioral changes like psychosis. Muscle wasting, shortening of clotting time, fragile veins, systemic super infections etc.

An analysis of non-prescription drugs dispensed by vaidus & other so-called experts was carried out in laboratory for presence of steroids. The Libermann-Burchard test was carried out for the purpose.

Out of 16 samples tested 10 samples shown the presence of steroids.

K_6 Scope of prescription to OTC switchover in India

Atri Banerjee*, Amita Mirani, S.S.Poddar

Principal K M Kundnani College of Pharmacy, 47, R G Thadani Marg, Worli Sea Face, Mumbai - 18

The official Indian OTC drug market stands at over $120 million as vis-à-vis the world OTC market worth $49.8 billion. Currently Indian companies are only using 4% of the 27% possible market.

The objectives of this work was to evaluate the prescription to OTC switch over in India, its repercussion in some of the prescription segments with a special perusal towards patient care &drug marketing status

The methodology was survey based & the data collected were critically assessed in order to evaluate the merits & demerits of prescription to OTC switchover Brand awareness of the product, lowered price, maximum reach and increased sales by the retailers supported the switchover and benefited the consumer while revenue protection would benefit the Pharmaceutical Industry.

It was found that alienating the doctors lead to high promotion costs of the products & self-medication detrimental for the illiterate discredits the prescription to OTC switchover in India.

It may be concluded from our research work that the prescription to OTC switch over may prove beneficial from a marketing viewpoint but it should be limited to a few drugs from the patient-interest point of view. The switch needs to be designed in a restricted manner and to be followed on careful guidelines.

K_7 Per capita expenditure on drugs in india-loopholes & ground realities

Vinita Katara*, Kunal Agrawal, S.S. Poddar

Principal K M Kundnani College of Pharmacy, 47, R G Thadani Marg, Worli Sea Face, Mumbai - 18

The Indian pharmaceutical market stands ninth in the world. The % of GDP that India invests on health is 5.2% which is in line with the WHO recommendations. This being contradictory to the fact that the annual Per capita expenditure on drugs in India is US $3 which according to the WHO and the WORLD BANK is amongst the lowest in the world. Over the years attempts have been made to steadily raise the Per capita expenditure on drugs in India. Like decontrolling drug prices by DPCO (drug price control organization) , US authorities claim that the "copycat" Indian pharmaceutical market is a major cause of the loss of foreign trade due to selling of generic substitutes at a cheaper price.

The OBJECTIVE of this work was to critically examine various factors associated with the per capita expenditure on drugs in India and thus to derive a conclusion whether, "the per capita expenditure on drugs in India is a yardstick to measure the nations well-being, or just a myth". Thereby suggest parameters by which the Per capita consumption of drugs can be raised by increasing accessibility of essential drugs.

Various opinions expressed by experts in pharmacy professions, lawmakers and economists were considered and economically evaluated. A survey for collection of facts related to income status, population status and socioeconomic conditions of different countries was undertaken for which the WHO, World Bank were consulted and eminent economists practicing in the Mumbai region were interviewed.

Thus to conclude the Per capita expenditure on drugs in India is a result of the low economy of the country, whereas the income to expenditure ratio on drugs is competitive to that of other countries. This study indicates that the per capita expenditure on drugs in India is not just the total expenditure on drugs/ the total population, but many factors have to be accounted for that are influencing this figure. Likewise the focus of the authorities should be on increasing the Per capita consumption of drugs by raising the accessibility of the essential drugs. Thus the per capita expenditure on drugs should not be used as the only tool to measure the efficiency of the health care system and the nations well being.

K_8 Assessment of needs of pharmaceutical services in jharkhand

Avijit Mazumder*, R. Mazumder, K.Jayaram Kumar, Juhi Sahay**

Department of Pharmaceutical Sciences, BIT, Mesra, Ranchi – 835 215.

Every state has a varied social and economic diversity of its own depending on which there is a variation in the needs of different pharmaceutical services. The pharmaceutical services can be improved if the degree of requirement alongwith the perceived strength and weakness of these services are known. We have conducted a survey to cater into the degree of various needs of the pharmaceutical services of the people of Jharkhand with a set of structured questionnaires. People lay utmost importance on the service of "convenience and advice from retailers on OTC and prescription drugs", may be to their tendency of self-medication and reliance on herbal remedies.

This service was followed by "easy availability of life saving drugs at low affordable cost" which was followed by the service of "safe administration of parenterals by pharmacists" as their third important choice of service. The fourth important service as ranked by the residents include "availability of toiletries, baby food and vitamins in the medical shop" which is followed by the "service of setting up of a pharmacy with modest facilities" and gradual increase in the accessibility of these facilities as the fifth choice in the ranking.

The professionals, on the other hand ranked "availability of high quality drugs at affordable cost" as the foremost important choice among all services required. The second important need as perceived by professional include "prevention of misuse of drugs by doctors/ pharmacists" as there are reported incidents of drug abuse and drug interaction in the state of Jharkhand. The third and the fourth important choice of service which should be highlighted include "safe administration of parenterals by experienced pharmacists" and availability of toiletries, baby food and vitamin in the medical shop respectively. The physician were found to strongly discourage the tendency of the residents regarding taking advice from retailers on OTC/ prescription products.

Easy availability of high quality medicines at reasonable cost, health for all, advice on probable drug misuse and interaction are some of the key points to be considered in our national health policy. We should simultaneously discourage the practice of self medication. The media should play a positive role in the public awareness of the national health policy framed as per the needs of different pharmaceutical services.

K_9 A study on drug management service in the government sector

S.C.Mandal[1]* & D. Chakraborty[2]

1. Indian Pharmaceutical Association,
2. Institute of Pharmacy, Kalyani, Nadia

Uneven access to medicines is a global problem, resulting in millions suffering due to non availability of treatment at the time of sickness. On the other hand a section of people are using medicines indiscriminately and, unnecessarily. It is required to adopt a rational drug management programme so that all or majority patients receive proper medicines at the proper time.

To assess the awareness of Pharmacists working in Govt. sector and to improve their knowledge about rational drug management for improving access to medicines.

A questionnaire was distributed to 180 Pharmacists working in different Hospitals & Health Centres throughout West Bengal covering 16 districts. Then they were imparted a training of 6 days and again asked to solve the same questionnaire. Their scoring was assessed and evaluated.

A six-day training course on rational drug management for working Pharmacists.

It was found after analysis that-

1. None of the Pharmacists are involved in Policy making with respect to selection & procurement of drugs.
2. Only 11% of them are involved in drug store management.
3. 56% are aware that the country has an essential drug list.
4. Only 26% are aware about rational use of drugs.
5. 50% are aware about the scientific procedure of inventory control.

Post training evaluation showed a sharp improvement to the extent of 100%.

The facts reflected by the results may be due to lack of awareness of the health Policy makers about the potential of pharmacists and non-inclusion of Pharmacists in formulating health Policy. Though the Indian Govt. has published a list of essential drugs 7 years back, sufficient steps for its popularization and implementation has not been taken. Also, current health aspects like concepts on essential Drugs & rational use of Drugs are not included in Pharmacy curriculum taught all over India, to a large extent.

Current health aspects like concepts of essential drugs, rational use of drugs and rational drug management is required to be incorporated in the Pharmacy curriculum. Pharmacists are required to be involved in selection, procurement & distribution of drugs for improving access to medicines. Govt. should involve Pharmacists in framing Health Policy and Drug Policy in all level for improving access to medicines.

K10 NDDS-will it strike the bull's eye? NDDS - A critical review

Gauri Sharma*, Mahendra Thakre

National Institute of Pharmaceutical Education and Research (NIPER), Dept. of Pharmaceutical management, Sector 67, Phase X, Mohali 160 062, Punjab

With the Pharmaceutical Industry heading towards post 2005 era, it has devised strategies, which are today perceived to help salvage the post 2005 storm of the product patent regime. The Paper is a critical review of the strategies like NDDS, which are today seen, with high level of optimism. The present report is an in-depth analysis of the present status and future prospects of NDDS, giving detailed view of the commercial benefits offered by the technology and at the same time critical examination of the "immense potential" perceived, in light of challenges/hurdles which the industry is likely to encounter in the actual realization of the 'apparent' benefits that the strategy will deliver. Also to actually understand the ground market realities in regards to performance of NDDS, a **market research project** was undertaken on the subject in parts of north India, also forms a part of the report.

The report has been divided into three sections.

- **The first section** gives a detailed review of the current status and future potential of the Global Drug Delivery Industry, current market potential-delivery route wise 2000/2005 & disease category wise, Commercial and Clinical benefits offered by the technology to the pharma companies and to the patients respectively. Further, this section answers questions like - What makes India a lucrative destination for NDDS development for both national and international majors.
- **The second section** of the report focuses on the challenges/hurdles in the development of NDDS, the Regulatory requirements for manufacture and standardization of NDDS and answers the questions like -Why Indian levels of NDDS research and market is very low in comparison to other countries, with special arguments in favor to strategies adopted by countries like US, Japan, Korea and Taiwan. Finally what measures India needs to take to improve this situation.
- **The final section** of the report presents the findings of the market research project undertaken to analyze the actual market perception for these new technologies employed in the conventional dosage forms.

With Indian pharmaceutical industry formulating strategies for growth and survival post 2005, the report gives **a comprehensive and critical analysis** of the strategy (NDDS) perceived to be one of the most promising strategies for a safe and prospering future. The report can help pharmaceutical companies decide their future strategies more wisely in light of both the negative and positive sides of NDDS so revealed, to meet the challenges thrown by post 2005 era.

K11 A survey on drug utilization pattern in the health care system of Orissa

[1]*Ranjit P. Swain, [1]D. Patra, [2]Pratap K. Sahu, [1]P. Mishra

1. University Dept. of Pharmaceutical Sciences, Utkal University, Orissa
2. Jayadev College of Pharmacy, Naharakanta, Orissa

Drug utilization pattern is an important factor determining the efficiency of a Health care system. An efficient health care system requires usage of quality drugs at an affordable price. Recently, only 40% Indians can enjoy the benefit of modern medicine. In order to reach medicine to remaining 60% of the population, judicious use of drugs is important. For this purpose it is essential to collect data to evaluate the Drug utilization pattern and to effect necessary interventions and policy changes to eliminate the shortcomings present, if any.

A model study was conducted at community pharmacies and health centres both in rural and urban areas of Orissa, covering major Hospitals. The survey was conducted over a period of 4 months involving 20 community pharmacies and 5 health centres. Data were collected from prescriptions served by pharmacies over 2 hours per day. Total number of prescriptions analysed in Health centre were 1600 and in community pharmacy were 1398.

Fixed dose combinations, frequency use of antibiotics, vitamin tonic and polypharmacy was the trend identified through this survey. The reverse trends were noted in use of antibiotics and use of generic drugs. Indiscriminate use of Antibiotics is leading to resistance development. Drug regulating authorities should consider these facts before approving final dose combinations. Health care professionals need to be educated in the rational use of drugs.

K12 Gender defined cataract surgical coverage in satara district, Maharashtra

S.B.Bhise [1], Abhijit D. Nalawade*[2], Amol Dhane [2], Vikas R. More [3]

1. Govt.College of Pharmacy,Aurangabad.
2. Govt. College of Pharmacy, Karad-415 124.

3. Jehanjir Hospital, Pune.

Women bear approximately two thirds of the global burden of blindness, with cataract being the major cause in developing countries and it is likely that much of the excess female blindness in these countries is due to cataract.

The paper gives the brief report of survey, which was carried out, in Civil Hospital of Satara to determine cataract surgical coverage rates by sex and the proportion of cataract blindness.

To identify cataract surgical coverage, we searched several patients' registers. A total of 578 cases were screened which revealed the following data: -

- Proportion of cataract blind in males and females was 145 and 217 respectively.
- Cataract operated cases included 107 males and 109 females.
- Cataract surgical coverage for males and females was 41.22 and 29.9 respectively.

We found that the cataract surgical coverage rate was higher for males than for females. Closing the gender gap could thus significantly decrease the prevalence of cataract blindness and gender sensitive intervention programmes are needed to improve cataract surgical coverage among females.

K_{13} Qa concept : independent and international

M. M. Borkar*, A. A. Shirwaikar, P. G. Shilotri, Simi Sharma

Wyeth Limited, Plot-L 137, Phase-IIIA, Verna Industrial Estate, Verna 403 722, Goa

Examination of the stringent regulatory and environmental requirements for manufacturing facilities, and rising GMP and GLP standards, provides a glimpse into the changes pharmaceutical companies are experiencing. Maintaining profitability requires proportionate increases in efficiency throughout the business. Individual departments contribute to productivity by fulfilling their responsibilities in serving immediate internal needs. They must also address external matters such as end-user needs and expectations. The balance of consumer issues and efficiency necessitate the development of an independent department to focus on product quality.

An essential element to develop and maintain safe, successful and ongoing business relationships with internal and external customers is the model, philosophy and concept of quality assurance that an organization adopts to consider all stages of product design and exceed customer specifications.

This article will characterize quality assurance, quality control, quality compliance and centralized documentation as separate entities with defined roles, and clarify the terms as they relate to pharmaceutical firms to effectively sort out many technical issues, which may or may not be addressed by differing international standards. In addition, the need for an independent quality assurance department will be discussed in context of its relationship with the quality control, quality compliance, centralized documentation and other internal customers such as marketing, medical, legal, product development, purchase, engineering, production and storage, distribution and human resources.

Although the functions of quality assurance, quality control and quality compliance vary, they can be held together as an integrated whole with centralized documentation to meet requirements for Good Documentation Practice.

K_{14} Succession of locums – implications for the continuity of service

Amit Jain*, Jayesh dwivedi,Udichi kataria, Rahul garg, Rajendra songara, Anju goyal

B.N College of Pharmacy,Udaipur (RAJ.) - 313001

Pricipally locum means being our own boss and having the ability to work when and where we like. The role of self employed freelance locum is likely to be the career choice in the future for an increasing number of pharmacists. If pharmacist is truly to be regarded as a member of the health care team, which seems to be an aspiration of the profession then continuity is essential.

Staff management, premises management, initiation and monitoring of charge, information technology, recruitment and all other little trifles of the job are not generally within the remit of locums. The multiplicity of such responsibilities which are almost beyond the ability to satisfy, is the reason why no body wants to do the job.

The problem with using a locum is trying to decipher their writing after they have left. A succession of locums can leave the notes almost impenetrable. One solution is to find a locum who has neat, legible handwriting.

It is belived that the Royal Pharamaceutical Society has not yet begun to consider the effect on the profession of a significant part of the pharamacist workforce operating permanently on a locum basis. The concept of pharmaceutical care howsoever we choose to define it, has one essential component and that is continuity.

K15 An attempt of development of community pharmacy practice: Results of two surveys and two workshops conducted in Tamil Nadu

A. Arunkumar*, S. Senthil Kumar, K. Masilamani, R. Manavalan and S. C. Basak

* Department of Pharmacy, Annamalai University, Annamalai Nagar 608002

The professional role of the Indian community pharmacists has only recently been recognized resulting in an all round focus on them. We designed this project to determine community pharmacists' current status regarding the delivery of pharmaceutical services with the specific intention of identifying deficiencies vis-à-vis legal requirements, and what are the interventions to be provided to improve the present situation. The project was carried out in Cuddalore district (Population: 22,80530; Per cent of rural population: 73.52; Area: 3,564 sq. km.; Pharmacies: 503) of Tamil Nadu covering urban, suburban, village and few remote areas. The sample for this study included 210 representative pharmacies in the district. The study team contacted the person in charge of pharmacy with a standardized questionnaire and interviewed him/her directly. The surveillance study was carried out in two phases. The two workshops were offered following each phase of survey study to provide opportunity to improve pharmacists' knowledge. The study found that pharmacies function without registered pharmacists in about half of the pharmacies at the time of study team's visit, more so in rural areas. More than 27% of the pharmacists (86% of the supporting persons) accepted the fact that they supply prescription drugs without a prescription. Over 60% of the pharmacists were not aware of the issues around rational drug use and essential drugs. Another significant observation was that the majority of consumers (70-80%) first seek advice about sexually transmitted diseases, menstrual disorders, contraceptive methods and minor illnesses from pharmacists. A total of 98% of the pharmacists (94.8% of the supporting persons) suggested medicines for the trivial and even advanced disease conditions simply by the indications of illnesses. As regards to educational workshops conducted for pharmacists, the attendees of the workshops felt strong willingness to participate such workshop to update knowledge. Significant improvement of knowledge and skill in pharmacists were observed on several measures.

K16 Validation: Smart ways to do

Y.S.Purai*, T.Ramesh, M. Varma, A.Tickoo

Drug Regulatory Affairs, Panacea Biotec Ltd. B-1, Extn/G-3, Mohan Co-Op. Industrial Estate, Mathura Road, New Delhi 110 044

A primary concern for corporations in the pharmaceutical industry is the assurance of product quality and confidence in their safety. "Validation program" is an umbrella term, encompassing the components like Validation Master Plan, Qualifications, Process Validation and Final Report.

If performing validation, the key functions that help to assure the quality as well as issues that must be considered when developing a validation strategy are Planning, Documentation, Implementation, Review and Approval.

Effective managing of time and effort in each of these functions will deliver good result. In the total validation period, it is important to allot the correct time to finish each activity. It is advisable to spend more time in documentation and development for effective validation.

In validation programme are lack of time, lack of personnel, lack of experience and knowledge, change process, Prospective and Retrospective validation, lack of implementation of validation and poorly designed documents.

- Assure some consistency by developing templates for documents like requirements, specifications, technical manuals, test plans, and reports, Preplan the validation with key stakeholders
- Recruit the right resources for the development of documentation and performance of testing.
- Establish a repeatable method for identifying the correct individuals needed to review and approve of deliverables.
- Allot ample time for the review and approval
- During lull periods and downtime communicate with key stakeholders and validation participants. Maintain their interest in the work that must still be done. Acknowledge obstacles and move on.
- Adjust your plan to changes and issues that are encountered throughout validation.

K17 Cleaning validation and its regulatory importance

S. Lakshmana Prabu*, Arun Shirwaikar, K.K. Srinivasan, R. Mahalakshmi, Shery Jacob

College of Pharmaceutical Sciences, Manipal – 576104.

In this presentation we shall share our thoughts on cleaning validation and its importance in pharmaceutical industries. The purpose of the cleaning validation is to prove the effectiveness and consistency of cleaning of the pharmaceutical production equipment to prevent the cross-contamination and adulteration of drug products with other active ingredients, unintended compounds or microbiological contamination. So it is necessary to validate the cleaning procedures to ensure the safety and purity of the product and regulatory requirement in Active Pharmaceutical Ingredients (API) product manufacture. The limits are determined by dose criterion or 10ppm criterion. The benefits due to cleaning validation are compliance with federal regulations, identification and correction of potential problems, previously unsuspected, which could compromise the safety, efficacy of drug products. Documents required for Food and Drug Administration (FDA) are SOP(Standard Operating Procedure) of the different cleaning process scenarios, responsible person who is performing and approving the validation study, specific written validation protocols, validation studies in accordance with the protocols, and final validation report approved by management. Validation report includes procedures used to clean, physical and analytical test results, acceptability of the result, relevant information during the validation, appropriate level of verification, review of any deviations for the protocol.

K_{18} Product management: important aspect of pharmaceutical industry

Bharti Ahirwar* and Dheeraj Ahirwar

Institute of Pharma Sciences, Guru Ghashidas V V, Bilaspur (Chattisgarh)

Product management as a separate wing is absolutely essential in an Organization. In order to manage any product a firm need to systematically develop the various elements of the marking programme, such as branding, segmentation, positioning and differentiation, new product development, distribution, Advertising, planning, price, sales management and marketing research. This constitutes the total marketing effort.

There are different types of product innovation some may demand only minor changes in technology whilest others may involvers more substantial innovations in technology and in turn create totally new market.

Product design process: it begins with the recognition of a need and ends with a manufactured product that is accepted by customers as being satisfactory in service.

The product manager's role is to develop product plan, implement them, monitor, the results and to task corrective actions whenever necessary. The process of developing new product embraces a variety of different tasks and functions. Companies focusing on such innovation strive to improve the price performance offering for their customers and marketing partners.

The classical innovation in product development -developing new application and customization integrating service into the product offering to the customer. Besides, it also includes the marketing function in the company including innovative way to manage promotions, channel partners and deliveries. Products managers have to regularly assess the sales and profits of each item in their portfolio in order to determine which items to build, maintain, harvest or divest. They should regularly review how each product is positioned against competitor products. They use of product mapping technique for identify changing market segment and develop new positioning strategies for reaching the target segments.

L_1 Regulatory perspectives on analytical method validation by HPLC

Rahul S. Songire, Akshay M. Baheti, Dr. Rajashree C. Mashru*

Principal K M Kundnani College of Pharmacy, 47 R G Thadani Marg, Worli Sea Face, Mumbai - 18

Test procedures for the assessment of the quality levels of pharmaceutical products are subject to various regulatory requirements like ICH, CDER, EURACHEM, TGA, MHCA and MCC etc. The opinions differ from the guideline to guideline about the determination of performance characteristics of the analytical method validation by HPLC hence the objective of the present work is to review the analytical method validation requirements of various regulatory authorities and to provide regulatory perspectives on performance characteristics of the method validation in such a way that the analytical data so obtained will fulfill the regulatory requirements of various guidelines.

Accuracy may be determined by % Recovery calculation of analyte in the sample, Precision may be determined by calculating the % CV of number of samples, Specificity may be determined by the Peak purity calculation , LOD & LOQ can be determined by measuring signals from the samples with known low concentration of analyte with those of blank samples, determination of the slope of the calibration curve and the standard deviation of the responses, Linearity can be calculated by determining the Linearity coefficient (r^2), Range can be determined by establishing Accuracy , Precision and Linearity for the analyte concentration in particular range, Ruggedness & Robustness by determining Accuracy and Precision at the changed parameters. All the method validation parameters are valid only when the system suitability is established throughout the analysis.

Thus the present work will enable the industries which are going for the Pharmaceutical product registration in number countries to obtain the data which will fulfill regulatory requirements of various guidelines with considerable saving in time and money.

L_2 Magic Remedies : Challenge to health profession and regulatory authorities

Ramchandra Patale*, Prashant Mande, Tejal Pandey, Lipika Chablani, S.S. Poddar

Principal K M Kundnani College of Pharmacy, 47 R G Thadani Marg, Worli Sea Face, Mumbai - 18

Inspite of significant advancements in medicine & pharmacy certain diseases remain incurable even today, which favours some opportunists to advertise & practice magic remedies. This is unethical & may prove to be dangerous, hence must be controlled to save people from their menace. The study was conducted to find out reasons for people diverting towards magic remedies & what pharmacist & regulatory authorities must do to control them.

The work was carried out through interviews in Mumbai.

55% of physician, opine they have less time to communicate & aware people, 43% said irrational drug combinations creating adverse effects hence people going towards other remedies. 70% pharmacist were found to be profit oriented, not socially motivated, 30% lacked support to carry out awareness programmes. 60% people go for magic remedies because medical treatment is expensive, 40% because of lack of health awareness. Regulatory authorities not working effectively to control advertisements & practice of magic remedies.

Inspite of Drugs & Magic remedies act, magic remedies are advertised & practiced because there is no definite cure for long term illnesses, health professionals lacking to create awareness in society, regulatory authorities are lacking to control such misconducts, resulting in economical loss to patient, professionals & degradation of image of health profession.

Magic remedies are challenge to our profession, pharmacist must play vital role to eradicate them by counselling patients providing drug information, arranging awareness programmes, assisting regulatory authorities & coprofessionals, by developing more lasting professional reputation. Regulatory authorities should implement rules strictly to control advertisement & practice of magic remedies.

L_3 "Strip Cuttin" - An upliftment in pharmacy practice or just an undue publicity

Amita Mirani*, Atri Banerjee, S.S.Poddar

Principal K M Kundnani College of Pharmacy, 47 R G Thadani Marg, Worli Sea Face, Mumbai - 18

The Maharashtra FDA in letter no: MEMORANDUM/158-03/8 Dated 29/4/03 has proposed to Retailer Drug Chemist Association (RDCA) that they should indulge in "strip cutting" even for schedule (Rx) drugs but RDCA has protested against this move of FDA & in response to their letter have sent a feedback to FDA dated 26th MAY '03 stating it wont be feasible for them to cut prescription strips & give them to consumers.

The prime **objective** of the work was to review the FDA rule & also the RDCA plea, to state pros & cons of strip cutting, to give suggestions that can be the best interest of patient, Government & RDCA.

The Methodology was survey based in which prominent professionals, retail drug store owners, pharmacists, manufacturing personnel, doctors were interviewed & conclusions were drawn.

Rational usage of drugs, reduction in cost incurred by the patient went along with the FDA preposition.

While sale of date expired drugs, habit forming drugs, spurious drugs, damaged packaging, non completion of desired regimen by patient, refusal by distributor to take strips back once cut went against the FDA proposal& supported the RDCA protest.

The suggestions to overcome the same:

1) Reduction in minimum unit pack.
2) Printing of details on each tablet pouch of the strip in well readable manner.
3) Attachment of chit with requisite information to cut strip with rubber band by Retailers.

Is the FDA right in its move or rules laid by it should be reframed? Though in developed countries entire strip have to be purchased but we need to analyze if what's good for developed countries is good for us as well? These are few questions yet to be answered.

L_4 Study of reported cases of spurious drugs

Jaya Bhatia[1*], Jay Visaria[1], Praveen Mundadhe[2], Manjiri Gharat[3], S.S. Poddar[1]

1. K M Kundnani College of Pharmacy, Mumbai - 18
2. FDA, Thane district

K M Kundnani Pharmacy Polytechnic, Ulhasnagar - 3

The aim of the present study was to carry out a study of reported cases of spurious drugs.

A methodology of conducting survey was employed. The Thane district of Maharashtra was identified as the area for investigation. Relevant personnel were contacted personally and administered with set of queries. The responses procured were statistically handled. The respondents comprised Industry and FDA personnel.

Information made available from Thane FDA regarding reported cases of spurious drugs over the last four years was analyzed.

They indicated between 1999-2001 only two cases of spurious drugs were reported. Subsequently between 2001 and March 2003 eight cases have been reported.

Detection of the spurious drugs was made possible due to presence of typographical errors ,erroneous entries on the label and other variations.

It was found that number of cases of detection of spurious drugs is on a steady rise. In less than 10% of cases of all substandard and spurious drugs, prosecution was launched. Legal action is pending in most cases. The national conviction rate for cases of spurious drugs is as low as 3%.This indicates that authorities need to work towards more stringent and effective laws. The ratio of 1 drug inspector to a 100 manufacturing units needs to be improved.

The study successfully identified that:-

1. Cases of spurious drugs are on an alarming rise
2. The government, regulatory authorities and industry must work together in order to crack down on spurious drug makers.
3. A need for a continuing education program designed by relevant experts for pharmacists on the identification, reporting and elimination of spurious drugs.

L_5 Dealth penalty - for spurious drug marker

Vijay D. Wagh[1], G.S. Asane*[1], S.R. Chaudhary[1], M.K. Samanta[2], M. Ravichandran[2], B. Suresh[2]

Department of Pharmaceutics,

1. Pravara Rural College of Pharmacy, LONI, Maharashtra.
2. J.S.S. College of Pharmacy, Ottacamund, Tamilnadu.

The thriving spurious drug traders in our country run abusiness of around Rs 4000 crore and come out with a clean profit of a whopping Rs 3000 crore. For, their investment in it is close to nil. Whereas, the whole gamut of pharmaceutical industry which is worth nearly Rs 20,000 crore, hardly ekes out a margin mere Rs 1600 crore annually on a average 10% profit line. According to a senior industry source, spurious drugs are normally sold in the northern belt (i.e., Punjab, Haryana, Himachal Pradesh, Delhi, Uttar Pradesh, Bihar and to some extent in Madhya Pradesh).

Lesser known, remote villages are the usual haunts of spurious drug sellers. However, the awareness about the incidence of spurious drugs among the doctors and the patients is not much. A recent study conducted by National Pharmaceutical Pricing Authority (NPPA) shows 94% of the doctors in the country hold the belief that there are no spurious drugs. And 97% of patients do not believe in the existence of spurious drugs.

It is myth that stringent regulation can put an end to the problem altogether. Law and regulation can definitely work. In Law, There is a death-penalty for a murder of a person. Here also spurious drug-makers

making same kind of crime or more than that they are playing with the life of patients in life threatening conditions. So, Death-Penalty will really work in some extent in such cases.

But the companies can work better. Drug-Makers should feel that their job is not merely to make and sell medications, but also to ensure that the consumer gets only genuine products. Medicines are unlike any other commodity. The next best things companies can do are creation of awareness among the masses.

L6 P.C.T.'s Role is beneficial in intellectual property rights for developing India

Vijay D. Wagh[1], S.R. Chaudhary[1], M.K. Samanta[2], M. Ravichandran[2], B. Suresh[2]

Department of Pharmaceutics,

1. Pravara Rural College of Pharmacy, LONI, Maharashtra.
2. J.S.S. College of Pharmacy, OTTCAMUND, Tamilnadu.

Intellectual property will be the main driving force in this area and WIPO's (World intellectual property organization) focus is to provide strong leadership in developing the intellectual property system with a view to underpin the global conditions where creative potential can be released and channeled into tangible, sustainable development.

PCT (Patent Co-operation Treaty) mainly intends to simplify and to render more effective and economical means of patent protection in multiple countries. PCT offers greater flexibility keeping potions open by making multiple designations and various possibilities for withdrawal at various points so that further expenses could be avoided. It provides for better quality translation for the national phase and better planning of the expenditures for the national phase. So, Developing India would find the cot control option attractively and beneficial.

India is one country which is blessed with so much of bio-diversity that it has already become the victim of large scale bio-piracy. India is one country where majority of the population sue and propagate indigenous knowledge for agriculture and medicine (health). This is the reason why it is still surviving is a highly competitive market without much of government sponsored social security benefits. The healthcare that indigenous systems like Ayurveda and tribal medicines are providing are worth billions of dollars in the market place of capitalist trade.

So, IPR could be a progress tool for India. We should be able to identify and articulate interests clearly and priotorise the action plan in the lights of today's changing world.

L7 Registration of pharmaceutical dosage forms, overseas

M. Varma*, T.Ramesh, A.Tickoo, Y.S.Purai

Drug Regulatory Affairs, Panacea Biotec Ltd., B-1 Extn./G-3, Mohan Co-0p. Indl. Estate, Mathura Road, New Delhi – 110 044

Registration of Pharmaceutical Dosage Forms with the Regulatory Authorities all over the World is through the submission of a set of documents compiled by the name Dossier.

The purpose of the article is to achieve greater harmonisation and uniformity in the interpretation and application of technical guidelines and requirements for a Pharmaceutical Product Registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of our article is to approach towards a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

The article presents the common format for the preparation of a well-structured dossier for applications that will be submitted to Regulatory Authorities, International. Regulatory review and communication with the applicant will be facilitated by a standard document of common elements. In addition exchange of regulatory information between Regulatory Authorities and the applicant will be simplified. Such a format if implemented will greatly improve the coordination and communication between the Regulatory Authorities and the applicant.

In lieu of this International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use is a unique example that brings together the Regulatory Authorities of Europe, Japan and the United States and experts from the Pharmaceutical Industry in the three regions to discuss scientific and technical aspects of Product Registration.

L8 Drug regulatory affairs in pharma education

Dinesh Kumar, Sheetal Guleria, Gaurav Narang, R. Sunil Kumar,* Priyanka Jain, Gulshan Kumar and Ranju Gupta

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh 160 014

Human and financial resources are critical for drug regulation and industries employ people with

required specialized knowledge and skills in Drug Regulatory Affairs (DRA) department. A trained professional in this area is an added asset for pharmaceutical industry but pharmaceutical companies face a dearth (shortage) of trained regulatory professionals as no course is available at undergraduate and postgraduate level in pharmacy curriculum, in academic institutes.

Drug Regulatory Affairs department is one of the important department in pharmaceutical industry. For marketing a medicinal product in the market approval has to be sought from the regulatory agencies. DRA covers all products for which medicinal claims are made, and all activities associated with drug manufacture such as importation, registration, distribution and promotion. Drug regulatory authorities all over the world are very vigilant about import of drugs. To weed out import of substandard and spurious preparations these agencies exercise strict control on importers. For import of drugs all these authorities have made the registration of product mandatory and the same is looked after by special dedicated agencies of each country. The essential part of registration requires dossier, which contains all the technical information about drug. The preparation of dossier is done by expert staff, which has sound technical knowledge as mistake in dossier can lead to rejection of application for marketing

With increasing demand for drug regulatory affair personnel in industry there is now urgent need for educating students about drug regulatory affairs in the academic institutes as a complete subject. Even though many aspects of DRA are being dealt in undergraduate and postgraduate syllabi in pharmacy education like cGMP, validation, quality control, quality assurance, packaging, clinical data of drugs, clinical trials, ANDA, tests on excepients, in-process quality control, still there is need to combine these topics and teach DRA as a separate subject. In addition topics such as ICH guidelines, Filing requirements in India, establishment licensing, standard operating procedures should also be included. Coordination between industrial regulatory affair department and educational institutes can also help to generate trained professionals with requisite skill to have effective drug regulation which will lead to improve quality standards of drugs as well as easy registration of drugs to be marketed in various countries.

L_9 Survey of prescription analysis in drug stores in Shirur Taluka of Pune District

Baheti D.G.*, Page A.B., Redasani V.K., Nawale S.M., Tare M.S., Neharkar V.S.

SCSSS College of Pharmacy, Shirur, (Pune), Maharastra 412 210

Self medication is rapidly increasing. People directly going to the Drug store and the Medicines without consulting with the Physician. Today Public became more knowledgeable and so they take the Medicines without understanding the Disease state and condition.

Our team conducted the Survey of Drug Stores in the Shirur taluka of Pune district. The Survey was conducted for analysing the Prescription from different Medical stores. Statistically we found that the Pharmacist running the Medical Shop supporting the Self medication to some extent. Some times they give Medicines without Prescriptions. This Survey was done in about 75 Medical Stores of different categories. It was observed that out of 50-60 Prescriptions per day; 60-70% drugs are sold on New Prescriptions 30-40% drugs are sold on Old Prescriptions and others are General items. It was also found that some times the Medicines are also sold by Physical appearance.

If such condition will continue a day come when the ratio of Drugs sold by Prescriptions and non-Prescriptions get imbalance. In such condition it is the role of Pharmacist to protect the Society from the adverse effects of the Drugs and help them to control the Self medication. So it is the duty of Pharmacist not to give the Medicines without Prescriptions. This step should be taken by the entire Pharmacist to get check on this severe problem and it should be started from his / her family members and friends.

L_{10} Role of MCA in developing countries

Sonu Verma*, Komal Balani, Madhu Gupta, Anita Sharma, Shikha Raheja, Anju Goyal.

B.N. College of Pharmacy, Udaipur (Raj.) 313001

The Medicines Control Agency (MCA) is an executive agency of Department of health. It plays vital role in ensuring the timely availability of new medicines of known quality, safety and efficacy. It is soon to be merged with medical devices agency but its functions and responsibilities with remain largely unchanged. The agency does not take. Funds from the government but is supported by the fees s it charges industry and others for service it provides.

The aim and function of MCA is to safeguard public heath by controlling medicines. It ensures that medicines sold or supplied are of an acceptable standard of quality, safety and efficacy MCA controls clinical trials, advertising and other promotional claims, quality control, manufacturing of products and the supply of imported medicinal products

MCA brings changes to legal classification. Source of enquires, patient information, control of advertising.

The MCA is formed of eight divisions including the licensing division, the post licensing division, inspection and enforcement division, executive support division, finance and human, resource division, general practice research Databases and information management division.

MCA play a vital role in health care program. It operates a system of licensing, classification, monitoring and enforcement of the medicines sold. It monitors adverse reactions to medicines and suspected defective medicines. It will safeguards standards for public health protection also discharges the function of the of the good laboratory practice monitoring authority.

So MCA acts as an integrated unit that ensures by its functions that medicines sold or supplied for human use are of an acceptable standard.

L_{11} Biomedical waste management

Girish H.*, Tina H. Bhatia, Monica Chauhan, Tejal, S. S. Poddar

K. M. Kundnani College of Pharmacy, Mumbai – 18.

The objective was to carry out a survey to get an insight into the current scenario of biomedical waste in the city of Mumbai and emerge out with the possible suggestion to improve the situation further.

A survey was done by interviewing the target respondents who were doctors, pathological lab personnel and hospital staff. Responses obtained were as follows: -

50% of the doctors and 75% of the pathological lab personnel expressed that they dispose off their waste in the common drainage.

80% of the doctors working in hospital hinted at the existence of a thriving "business" of hospital waste and most probably the sanitation staff of the hospital were involved in this business and complained that some of the waste do get smuggled out of the hospital and are used in the recycling business.

It was alleged that certain pharmaceutical companies were too happy to buy these waste (e.g., vials and syringes) at cheaper rates.

The best options in the waste management hierarchy sciences and technology, the industry and society all have to play critical role towards waste reduction. This means that people would enjoy a good quality of life.

L_{12} Indian pharmaceutical industry and new schedule M: An overview

T.Ramesh*, M.Varma, A.Tickoo, Y.S.Purai

Drug Regulatory Affairs, Panacea Biotec Ltd., B-1 Extn./G-3, Mohan Co-op. Indl. Estate, Mathura Road, New Delhi – 110 044

The Indian pharmaceutical industry is a success story worth have around $ 6 bn. today and expected to be $20 bn. by 2010. This sector is highly fragmented with more than 20,000 registered units in which leading 250 companies and another 8000 Small Scale Industries forms the core of the industry.

It is estimated that in between 2002 to 2007, around $ 82 bn. of branded products will go off patents giving good opportunities in tapping generic market for Indian companies. At present it is exporting API and formulation worth of $ 2 bn., which needs to go a long way to get a reasonable share of the generic market in next five years.

The post 2005 product patent era is going to definitely impact the performance of Indian Pharmaceutical Industry where no more reverse engineering process will help. In the absence of strong research base, manufacturing facilities compliant with international standards and strong financials, small scale industries will find it difficult to survive in the future.

Still the low costs of production, low R&D costs, skilled manpower, strength of national laboratories and an increasing balance of trade, relaxation on DPCO front, manufacturing facilities of international standards the post 2005 regime is well set to take on the international market.

Arrival of New Schedule M and the core competencies will play an important role in determining the future of many Indian companies. Invest heavily in R&D, merging and acquisition are the some ways to stay competitive in the future.

No compromise on implementation of Schedule M

Dead line for the compliance of revised Schedule M 31st Dec. 2003 is ahead. Even though it is tough, in this case all Pharma companies should be complied. For the sake of small-scale industries already the deadline had been extended 1 year, which is fair enough to those who really want to comply. Asking for more time is not seems good for pharma industry which is going go face touch challenge after 2005 and it is merely ignorance for compliance. It is not the time to think about the business but quality and human lives.

Government should not be linier but stringent to enforce this matter with the separate wings of inspectors, proper planning and inspection.

Financial packages to help small-scale units will be the great service from the government. Prompt implementation of this order will give great confidence to the customer as well to the Indian Pharmaceutical industry.

L13 Web-based clinical trials-a cost-effective approach

Vijay D. Wagh[1], R.B. Lawre[1]*, S.R. Chaudhary[1], M.K. Samanta[2], M. Ravichandran[2], B. Suresh[2]

Department of Pharmaceutics,

1 Pravar Rural College of Pharmacy, LONI, Maharashtra

2 J.S.S College of Pharmacy, OTTCAMUND, Tamilnadu

Pharmaceutical companies quickly patent any new drug formulation that is invented by them to protect their intellectual property (I.P). As per FDA regulations, the new drug has to be subject to three distinct phases of trials before it can be approved for consumption.

The development phase including the trial process usually consumes two third of the patented period. It is no secret that a pharmaceutical company makes most of the profit from its products during the patented period as the price of a drug drops drastically when the patent period ends and faces open competition.

Web-based Clinical trials are proving to be the right solution to meet this challenge. The use of web-based trial management systems, in case of large trials, have resulted in compressing the duration of clinical trials anywhere from two months to more than a year.

In addition to the time-saving, web-based clinical trials also provide other direct cost benefits like saving on printed stationery. The cost of printing Clinical Record Forms (CRF) that are used to capture clinical data, for a single patient participating in a trial could be as high as 5,000/- rupees.

Interactions of web-based trial management systems with interactive voice response systems (IVRS) and electronic patient diaries (EPD) are the emerging trend in the industry. These technological solutions open up more and more efficient ways of conducting clinical trial, which means accelerated advancements in ultimate patient care.

L14 Health insurance: It's status in India

Zarna Pandya*, Urvi Doshi, S.S. Poddar

Principal K M Kundnani College of Pharmcy, 47, R G Thadani Marg, Wori Sea Face, Mumbai - 18

Over the last 50 year's Indian healthcare industry has developed significantly. It is worth Rs.96,000 crores now and is estimated to grow at Rs.10,000 crores annually. The present exercise was undertaken to review the status of health insurance sector in India-opportunities it provides, challenges it poses and concerns it raises.

The study was carried out by referencing to texts and interviews with personnel's involved with health insurance sector in India. An open form of interviewing methodology was practiced for qualitative research.

The study indicated that, in the past, government controlled the health insurance sector, and its development was significantly less due to lack of competition. The economic policy reforms in the late eighties paved way for privatization of this sector. Currently there are three basic schemes available in India, providing various types of coverage's:

- **Government funded scheme**: e.g. Government health scheme, employees' health insurance scheme, etc.
- **Market based scheme**: eg.mediclaim schemes provided by Life Insurance Corporation of India, General Insurance Corporation, etc.
- **Member based organization**:eg. Schemes run by various NGO's e.g. SEWA, AKHSI, etc.

Latest developments in this sector are Cash Less Services and Third party Insurance. Insurance system in India has many drawbacks, such as: lack of awareness, misuse by doctor's and patients, improper financial scheme management, increased cost of healthcare, etc.

Given that the government has liberalized the insurance sector, its privatization and development, if well managed can improve health status in India very rapidly.

L15 Banned drugs: Current national status

Zaina P.Q.*, Manjari G., Poddar S.S.

Principal K M Kundnani College of Pharmcy, 47, R G Thadani Marg, Wori Sea Face, Mumbai - 18

Regulatory control over the manufacture and marketing of drugs seems to have taken a backseat as there are drugs being prescribed, marketed and sold in India today that are banned internationally. Thus the objective of our study was to find out the status of drugs banned all over the world but prevailing in our country.

The study included obtaining information regarding the drugs banned internationally from internet, books, journals and periodicals. A well-designed questionnaire was circulated among doctors and regulatory officials. Feedback was analyzed and quantified using appropriate statistical techniques.

Some of the drugs found which were banned internationally but found in India were: Analgen, Cerivastatin, Droperidol, Furazolidone, Lynestrenol, Nimesulide, Nitrofurazone, Phenformin,

Phenolphthalein, Phenylbutazone, Piperazine, Quiniodochlor, etc. from the survey conducted 88% of doctors were aware of the international ban on such drugs. 80% knew their colleagues prescribed them. 60% confessed to prescribing these drugs themselves. Reasons given were efficacy and cheapness of drug. Clinical experience of all these doctors had no cases of side effects. FDA officials said that their method of approving a drug was based on a rational approach keeping in mind the socio-economic background of patients. Following conclusions were drawn from the study:

1. Ban on drugs internationally is due to difference in final stage of clinical trials when tested on patients there.

2. Developed countries can afford to ban drugs with less regard to economic stature of the patient.

3. India being a developing country socio-economic background of the patient becomes important consideration.

4. Due to the numerous epidemics that are widespread in India, in comparison to developed countries the above mentioned drugs are a boon to patients here.

5. The prevalence of these drugs may also be due to the many drug lobbies that dominate the regulatory policy makers.

6. Corruption of the regulatory professionals at all levels of the regulatory agency hierarchy.

7. Develope countries "dump" their banned drug stocks in India because the latter is a developing country.

Scientific Poster Presentations

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AP$_1$ Cholesterol induced destabilization of liposomes produced by freeze-thaw extrusion

Sunil Agrawal*, G. Subramanian, Srinivas Muthalik, Roopa Karki and N. Udupa

College of Pharmaceutical Sciences, MAHE, Manipal

Liposomes are microscopic vesicles consisting of membrane like lipid bilayers surrounding an aqueous media. Most of the liposomal preparations involve freeze-thaw and extrusion methods. Cholesterol is an integral component in many liposomal formulations and is likely to influence the vesicular properties of liposomes produced by freeze-thaw extrusion. Laser diffraction particle size analysis showed that the volume median diameter (VMD) of freeze-thawed egg phosphatidylcholine multilamellar vesicles (eggPC MLVs) was increased when cholesterol was included in the bilayers. Using a freeze-thaw cycle of three minute freezing in liquid nitrogen at –196°C followed by three minute thawing at 50°C resulted in an anomalously large particle size for eggPC/chol formulations. The observed increase in mean size for eggPC MLVs when cholesterol was included indicates that larger structures were formed, which may have been due to aggregation and subsequent fusion of vesicles. The mean VMDs of eggPC MLVs increased after one freeze-thawing cycle, but did not change significantly between one and 10 cycles. However, the mean VMD of eggPC/chol MLVs increased following the process up to five cycles. Subsequent increase in the number of cycles produced no significant change in vesicle diameter, indicating an equilibrium situation after which further freeze-thaw cycles had little or no effect on the mean diameter for these liposomes.

AP$_2$ Performance evaluation of rapidly disintegrating tablets containing polyethylene glycol and meloxicam

Vikram Shenoy, Vasudha Bakshi, Sunil Agrawal and S. Pandey*

Department of Pharmaceutics, College of Pharmaceutical Sciences, MAHE, Manipal

Solid dispersions of Meloxicam in polyethylene glycol 6000 were prepared using various concentrations of the polymer by fusion cool method with the aim to increase the drug aqueous solubility. These solid dispersions were characterized by FT-IR spectroscopy and found that there was no chemical interaction between the drug and polymer. The fast dissolving solid dosage form was prepared by directly compressing these solid dispersions with the superdisintegrant, Ac-di-sol. These formulations were evaluated for physical parameters like hardness, friability, weight variation, disintegration time, drug content and found to be within the pharmacoepial limits. An increase in the in-vitro dissolution rate was observed in comparison to the commercially available conventional solid dosage form. Pharmacodynamic studies (Carrageenan induced rat paw oedema volume reduction) were conducted in Wistar rats where the anti-inflammatory activity of the solid dosage forms containing the solid dispersions was found to be significantly higher in comparison to the commercially available conventional solid dosage form ($P<0.05$).

AP$_3$ Formulation and evaluation of unit moulded jelly containing herbal medicament for mouth ulcer treatment

N.H. Indurwade P.S. Kawtikwar*, R.B. Belapure N.V. Janbandhu

S.N.Institute Of Pharmacy, Pusad-445 204, Dist.Yavatmal. (M.S.)

Mouth ulcer is a very common disease. It is a disease of oral mucosa characterized by small whitish ulcerative lesions surrounded by a red border (aphthae). Present marketed gel preparations are to be applied to the affected part either by finger or cotton plug, which may lead to enhanced irritation and inflammation of the already sensitive part. Therefore, an attempt has been made to formulate such a jelly, which will dissolve slowly releasing a herbal drug when held in contact with affected part with the help of tongue. The herbal drug *Tinospora cordifolia* has been incorporated which has both anti-inflammatory and anti-infective activity.

In contrast to the gel preparations which are difficult to apply, not capable of dose measurement, not to be swallowed, not capable to remain stuck at the lesion, the unit moulded jellies are stiff, integrated, slowly dissolving, having pleasant taste, held close at the lesion thus delivering the drug and relieving, harmless even if swallowed, stable, capable of carrying anywhere conveniently and so on.

A unit moulded jelly formulation containing *Tinospora cordifolia* was prepared and evaluated for its physical properties such as solubility, integrity/ fragmentation, transparency, taste, and appearance. It was also evaluated for anti-inflammatory activity by using score system in the human volunteers. The preparation has been found to be stable at 35° C for six month.

AP4 A compaction process to enhance solubility of ketoprofen using d-mannitol

Vijaya Kumar S.G.[1], Singh S.K.[2], Parveen Goyal[3], Ajit Singh[4] and Mishra D.N.[2]

1. Sanjivani College of Pharmaceutical Sciences, Rajota Khetri, Rajasthan-333 503.
2. Faculty of Pharmaceutical Sciences, Guru Jambheshwar University, Hisar-125 001.
3. Lord Shiva College of Pharmacy, Sirsa- 125 055
4. Government Institute of Management and Pharmacy, Adampur, Haryana.

The common approach to improve the dissolution rate of poorly water-soluble drugs and thereby improving bioavailability is by formation of solid dispersion. The purpose of this study was to develop a technique to enhance the dissolution rate of poorly water-soluble drug, ketoprofen with D- mannitol without the use of solvent or melting.

Compaction dispersion was prepared by compressing the physical mixtures of ketoprofen and D-mannitol this is crushed, pulverized, and seived to get 75-150 mm size. Dissolution testing for compacted powder was performed on USP Apparatus II, 100 rpm, 900 ml. phosphate buffer pH 7.4. The compaction process enhanced drug dissolution relative to drug alone and also relative to physical mixtures. While solid dispersion prepared by solvent method pocesses higher drug dissolution than the compaction dispersion. However, during formulation difficulty in complete removal of solvent regulatory requirements to have solvent free products are the hurdles in solvent method.

The compaction method in this study may provide a lower cost, quicker, readily scalable alternative for formulating ketoprofen or even any poorly water soluble drugs.

AP5 Design and evaluation of transdermal drug delivery system of theophylline

Jeyaverapandian. M.[1], Vijaya Kumar S.G.[1], Rajagopal. K.[1], Vijayaraj kumar P.[1], and Kasture. P.V.[2]

1. Sanjivani College of Pharmaceutical Scinences, Rajota Khetri, Rajasthan-333503.
2. Govt. College of Pharmacy, Karad, M.S.-415124.

Theophylline, a xanthine derivative still plays a prominent role in the management of acute chronic asthma and apnoea for prematurity. It is metabolized in liver and there is considerable variation in half-life. Frequent dosing is needed in chronic condition while it has narrow therapeutic range. Transdermal films of theophylline were prepared with the purpose of delivering the drug directly in to the systemic circulation in a controlled manner with in the therapeutic range with a concomitant decrease in dose.

Polymer matrices were fabricated using Cellulose Acetate Butyrate (CAB) and Poly Vinyl Pyrrolidone (PVP) by using Di Butyl Pthallate (DBP) as plastilizer in mercury substrate method. The formulations were subjected to evaluation methods to borne the thickness uniformity weight uniformity in contents, tensile strength, moisture uptake, non-irritancy, stability, etc.

In-vitro permeation studies were carried out in Keshary- Chein cell across human cadaver skin using phosphate buffer (pH 7.4) at 37 ± 0.5°C for 12 hrs., which showed a significant permeation potential for theophylline. Increase in the concentration of PVP in polymer ratio, plastilizer had significantly increase the cumulative amount permeated. The primary skin irritation studies did not reveal any irritation after application of the films on the skin of the rabbits and it was found to have sufficient shelf-life.

AP6 Design and evaluation of drug delivery system for non-surgical treatment of periodontal diseases

Vasudha Bakshi, N.M. Harish, M. Sreenivasa Reddy*, N. Udupa and S. Pandey

College of Pharmaceutical Sciences, MAHE, Manipal 576 104

For treating periodontitis, repeated and long-term use of systemic drugs is fraught with potential danger including resistant strains and superimposed infections. Local administration with controlled release delivery systems provides a useful answer to these problems. In the present investigation, an attempt was made to design, optimize and evaluate a controlled drug delivery system containing anti-inflammatory agents for their direct placement into the periodontal cavity and evaluate its performance in clinics.

The formulations were devised in the form of in-situ gels containing flurbiprofen using poly (DL-lactide-co-glycolide) (PLGA) as polymer. Prepared formulations were evaluated for its syringeability and drug content. The effect of various precessing parameters such as polymer vehicles, polymer concentration, co-polymer ratio and effect of formulation excipients on the drug release profile were comprehensively evaluated. Prepared gels were found to be uniform in drug content and could be easily extruded through syringe with 22 gauge needle. After the preliminary investigation, NMP was chosen as a vehicle for polymer. The in-vitro release studies indicates that the drug release occurred in a biphasic manner characterized with an initial burst effect followed by a slow release for a prolonged period of time. Release data indicates that the drug was released by first order kinetics and diffusion. As the polymer

concentration increases, the release rate decreases. The rate of drug release from the formulations prepared with the copolymer ratio of 65:35 was faster than that of other two formulations. The drug release was enhanced after addition of water-soluble additives like sodium chloride and mannitol in the formulations. Comparison of clinical results reveals significant improvement in clinical parameters such as gingival index, plaque index and reduction of the pocket depth.

AP_7 Solid-state properties of magnesium stearate and impact on its performance

Phanidhara Rao Katamraj* and Arvind K. Bansal

Dept. of Pharmaceutical Technology (Formulations), National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, SAS Nagar, Punjab 160062

Magnesium strearate is the most commonly used excipient in tablet manufacturing for the purpose of reducing the frictional forces between the die wall and in between the granules. Source of stearic acid and the method of manufacture of magnesium stearate are the potential causes for the variability in the properties of magnesium stearate. Apart from this, solid -state properties of magnesium stearate like particle size, surface area, particle shape and degree of hydration critically affect the performance of magnesium stearate. Magnesium stearate was procured from 6 different sources and evaluated for lubrication potential using Force - distance compression profiles on Texture Analyzer, flowability and other powder flow parameters. These difference in performance will be correlated with the solid state propertise.

The concentration of magnesium stearate was 1% and it was mixed with Dicalcium phosphate. Mixing, blending process, blending time , fill weight and bulk density of the blends were kept constant to avoid variations other than the grade of magnesium stearate. During compression, the maximum force was kept constant at 100N and distance traveled by the punch to achieve the force was determined for the blends having different varieties of magnesium strearate. To achieve equal bulk density, blends were precompressed and this precompression phase was also accounted by another set of experiements where in the distance traveled by the punch was kept constant. Besides this Carrs's Index and Hausner ratio were also determined for all the varieties. Area under the curve and time to reach the maximum force were set as criteria for the evaluation. The difference in lubrication performance will be correlated with the solid-state properties of the magnesium stearate.

Best varieties show significant difference in AUC values as well as time to achieve the maximum force as compared to inferior varieties. The value of AUC for the best grade was found to be 491. 621 N-sec and that of worst grade was 443.818 N-sec. The time values to acheive the maximum force, for the best and worst performed grades were found to be 7.822 and 6.786 secs respectively. The increase in bulk density was found to be lesser in case of better performers as they are already packed as they poured. It was supported by the fact that the fill weights were different (671 mg for the best grade and 640 mg for the worst grade) when blends having different grades of magnesium strerate were transferred into the die before the test was started.

It has been found that force distance curves using texture analyzer can be used as good tool to differentiate the good performers from that of bad performers of magnesium stearate. Solid state properties like particle size distribution, particle shape, surface area, and degree of hydration critically affect the performance of magnesium stearate.

AP_8 Characterization and evaluation of pancreatin microspheres prepared by emulsification–phase separation and solvent evaporation techniques

Rupali Meshram*, Amrita Bajaj, Rajakumari, A.

C.U.Shah College of Pharmacy, SNDT Women's University, Mumbai-400049

Pancreatin microspheres were prepared by emulsification phase-separation and solvent evaporation techniques using Hydroxypropyl-methylcellulose phthalate(HPMCP) as enteric polymer. HPMCP circumvents gastric inactivation of enzymes, and provides optimal mixing with chyme, a pre-requisite for effective enzyme replacement therapy.

Stability of Pancreatin enzymes–lipase, amylase and protease in polymer solvents–acetone and IPA was evaluated. Process was optimized for different core-coat ratios and 2^2 factorial design was used to study effect of process variables– surfactants/dispersants(X_1) and stirrer speed(X_2) on particle size. Optimized batches were characterized for flow-properties, acid-resistance, SEM, DSC and release kinetics at varying pH conditions to simulate duodenal conditions in patients with exocrine insufficiency. Combinations of Pancreatin and Omeprazole microspheres were formulated to assess role of Omeprazole in inhibiting acid environment in stomach.

Enzyme activities were retained intact in acetone-IPA(5:1). Microspheres with core-coat ratio(2:1) indicated acid-resistance to the extent of 85-95%. Stirrer speed & surfactant/dispersant concentration had significant effect on particle size. Microspheres prepared by both the techniques released enzymes in 5min. at pH-6.0 & above. Alkalinization of dissolution media promoted release of enzymes. The enzyme release

profile was found to be better with Microspheres as compared to conventional Pancreatin tablets.

Dissolution characteristics at different pH conditions and combination therapy with Omeprazole results in better tailoring of enzyme replacement therapy.

AP9 Desorption as a stress to evaluate O/W emulsion stability using zeta potential as a parameter

Nagaraj B., Gopinath D., Rambhau D., Apte S.S.*

University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, A. P. India.

Since desorption stress can be induced in emulsions by serial dilution, we have evaluated the possibility of using Zeta Potential as a parameter to monitor desorption stress with a view to predict the stability of o/w emulsion. O/W emulsions of sunflower oil and liquid paraffin were prepared with a blend of nonionic emulgents (Tween - 80 and Span - 80) with varyjng HLB values. 15% w/w of oil phase and 3% w/w of emulgent blend were used to prepare emulsion by phase inversion technique. A portion of resultant system was kept raw and the other was sonicated. Prepared emulsions were serially diluted (1:2000 to 1:64000) to induce desorption. Desorption was monitored by measuring Zeta Potential of the diluted systems using Zeta Sizer or Zeta Meter. Effect of HLB, concentration of emulgent and ageing on stability of emulsions was assessed by this technique. Droplet size changes with ageing were followed by photon correlation spectroscopy. For freshly prepared emulsions, patterns of Zeta- Potential changes with HLB shows a minimal value at HLB-II and 7 for liquid paraffin and sunflower oil emulsions respectively. These appear to be the required HLB values for the respective oil phase. These patterns were consistent with ageing persistent drop in Zeta Potential under desorption stress also showed minimal fluctuations at these HLB values on ageing. On variation in emulgent concentration at the required HLB values, minimal changes in persent drop in Zeto Potential were observed, under desorption stress at a certain concentration range indicating the usefulness of this technique even in predicting optimum contraction for a given oil phase. Physical observations like creaming, globule size changes were in agreement with the above observations. Zeta Potential can be used as a parameter to evaluate the stability of emulsions under desorption stress. The technique seems to be more acceptable than the stress conditions employed earlier to predict the emulsion stability.

AP10 Microemulsion based gel of methyl sulfonyl methane

M. Srinivasa Reddy*. Jessy Shaji

K.M. Kundnani College of Pharmacy, Mumbai

Methyl sulfonyl methane (MSM), a nutritional supplement that supplies biologically active sulfur which is an effective solution for many inflammatory conditions including degenerative wear and tear arthritis, rheumatoid arthritis, carpal tunnal syndrome, temperomandibular joint syndrome. Currently most of the marketed topical MSM formulations are available in the form of gels and lotions. These dosage forms have a limited penetration through the stratum corneum. Microemulsion based gels are the appropriate drug delivery system for prolonged and enhanced delivery through the skin.

The objective of present work was to develop w/o microemulsions as topical drug delivery vehicle to achieve optimal localized concentration. Water in oil microemulsions were formulated using plurol isosterique, plurol oleique, labrasol as surfactants,miglyol812 and isopropyl myristate as oil phase,water as aqeous phase. Microemulsion existing areas was determined by constructing pseudoternary phase diagrams using titration method .Microemulsions were evaluated for transparency, birefringence, thermodynamic stability and drug content. Microemulsion based gels were prepared by using aerosil 200 as a gelling agent. Microemulsion based gels were characterized for viscosity, clarity drug content,pH.

Microemulsion based gel revealed potential substitute for existing formulations achieving enhanced penetration and which is economically viable.

AP11 Effect of sodium bicarbonate placed at different configuration on performance of floating tablets

N.R. Shinde*, A. Gadhe, S. Patil, Y.L.Patel and A.P. Pawar

B.V.D.U. Poona College of Pharmacy, Erandwane Pune - 411038

Balloon type of Hydrodynamically Balanced System (HBS) is found to have best buoyancy characteristics. However, incorporation of gas generating agent is found to give steep drug release, burst the rate controlling system or change microenvironment pH. An attempt is made to study properties of HPMC based HBS by placing sodium bicarbonate (SB) at different configurations. The ring, bilayer and matrix tablets were prepared using SB, Diltiazem HCl (120mg) and excipient mixture (HPMC

K4M, HPMC K15M, lactose). Tablets were evaluated for floating, hydration and drug release properties.

All formulations remained floated for more than 8hrs. Matrix tablets showed good matrix integrity. Irrespective of concentration of hydrophilic polymers and lactose, the ring type of tablets showed the fast and maximum water uptake. After constant zone of maximum hydration, the fast erosion is observed in bilayer tablet. The order of hydration was - Ring > Bilayer > Matrix.

Bilayer tablets showed faster and maximum drug release and the order of drug release was-bilayer > ring > matrix. The Korsmeyer - Peppas constant 'n' was in correlation with the hydration properties of the tablets and values ~ 0.5 attributed to both maximum water lodging and drug release by diffusion. The 'n' values < 0.45 and fast drug release is attributed to gel erosion owing to contribution of SB and lactose.

The configuration of SB in the tablets showed significant effect on both floating characteristics and drug release. Ring type of tablets showed maximum hydration and slow release as compared to bilayer. Matrix type of tablet showed maximum drug retardation.

AP12 To study the effect of crystal habit of metronidazole

S. Kamtane[1], A.G Chopade[1]*, S.N. Sakarkar[1], S.V. Pund[2], A.D. Deshpande[1] and A.K. Dorle[3]

1. Dr. D.Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri , Pune- 411 018.
2. Dr. D.Y. Patil College of Pharmacy, Pimpri, Pune- 411 018.
3. Department of Pharmaceutical Sciences, Nagpur University, Nagpur- 440 010.

Crystallization is the process of obtaining relatively pure form of the solute material, which is having a definite physicochemical property, such as solubility, density, melting point, dissolution rate, transition point, plasticity, hygroscopicity, chemical reactivity which is due to crystal packing, molecular conformations, and lattice energy. These parameters define the technological and biopharmaceutical properties of active ingredients or excipients as compactibility, dissolution rate, bioavailability, pharmacological activity, stability, etc. The change in crystallization conditions promotes change in the relative development of the crystal faces, which may in turn change the technological and biopharmaceutical properties. Crystallization of Metronidazole was carried out in various conditions as change in solvents (water, ethanol, methanol, etc.), temperature, pH, agitation etc. and the crystal properties were studied as particle size distribution, dissolution studies, DSC, hot stage microscopy, X-ray crystallography. The studies reveal metronidazole exists in two polymorphs I and II. The polymorph II was found to be more stable than I. Equilibrium solubilities indicate that the solubility of form I is greater and faster than form II. The dissolution of II was found to be less as compared to I. The powder X-ray diffraction spectrum of the two polymorphs shows distinct differences in the arrangement of the molecules in the crystal lattices. Form I can be therefore taken for drug formulation for better bioavailability of the drug.

AP13 Divisible Sustained Release Tablets: A Breakthrough in Patient Compliance

Jitendra R. Patel*, Ramadas N. Kale, Milind R. Redkar, Padma V. Devarajan.

Pharmaceutical Division UICT, Matunga, Mumbai 400 019

Metoprolol tartrate (MT) is widely used in the treatment of hypertension, angina pectoris, and myocardial infraction and is normally recommended in dosage of 50 mg and 100 mg as a sustained release (SR) once a day formulation. Divisible tablets, which could offer two of the above strengths in one dosage form, could prove an economic advantage to the manufacturer and patients with enhanced patient compliance. A serious problem on physical division of a SR tablet, is enhanced release rates from the half tablets. The present paper deals with the formulation of SR tablets of MT containing two dosages in one dosage form. An innovative punch design was used in the development of divisible tablet to achieve comparable drug release rates from whole and half tablets.

Divisible SR tablets were prepared by wet granulation method. Effect of polymers, punch shape and pH on invitro drug release were evaluated. A novel method of quantifying "fracture" produced upon breaking of tablet was devised using a projection microscope. Fracture studies revealed nature of polymer-influenced divisibility of the tablets. The tablets were evaluated for stability as per ICH guidelines. Physical and chemical stability of the developed formulation was confirmed.

Stable SR MT tablets showing comparable in vitro release from whole and half tablet. Moreover tablet formulation was optimized to obtain pH independent release. Divisible SR tablets of MT showing pH independent release were successfully designed through innovative punch design and formulation optimization.

AP14 Novel approach to zero order drug delivery via hydrogel for verapamil hydrochloride

Ch. Niranjan Patra*

College of Pharmaceutical Sciences, Mohuda

In the present study, matrix tablets of Verapamil hydrochloride were formulated using hydrogels like

Hydroxy propyl methyl cellulose (HPMC) and Sodium carboxy methyl cellulose (NaCMC) with the aim to attain zero order release.

Verapamil hydrochloride tablets were prepared by wet granulation technique. Formulations F1,F2 and F3 contain drug: HPMC in 1:1,1:2 and 1:3, F4,F5 and F6 contains drug: NaCMC in 1:1,1:2 and 1:3 and F7 contains a combination of drug: HPMC: NaCMC in 1:1:1 ratios. The tablets were evaluated for hardness, drug content, and degree of swelling, In-vitro release study and permeability.

FT-IR spectra showed no evidence of formation of solid complex or any chemical interaction between drug and polymers. Analysis of variance (ANOVA) showed a highly significant difference among formulations at $p < 0.001$ level.

Hardness and drug content were with in the limits. The release rate was found to be decreasing as the concentration of polymer increased. This is due to the reason that the swelling degree is less because of higher concentration of polymer. Drug release from F7 followed a zero order release, which may be due to constant diffusion path length. All the formulations followed Higuchi's diffusion mechanism. The drug diffusion coefficient was found to be decreasing with increase in polymer ratio. Koresmeyer and peppas equation revealed that F1, F2, F3, F4 and F7 followed Non-Fickian diffusion whereas F5 and F6 followed super case II transport. Therefore hydrogel matrices in appropriate proportions are suitable for formulating controlled release tablets to have a zero order release for water soluble drugs like Verapamil hydrochloride.

AP 15 A novel sustained release formulation of tramadol hydrochloride using gellan

Soja Sreenivasan*, Nilani S. Tharan and A.K. Chandrasekharan

PSG College of Pharmacy, Peelamedu, Coimbatore - 641004

Tramadol hydrochloride is a centrally acting analgesic for moderate to severe pain. The plasma half-life of the drug is short (5-6 hours) necessitating frequent dosing (50 mg q.i.d) which may lead to poor patient compliance. Gellan is an anionic heteropolysaccharide produced by aerobic fermentation by Pseudomonas elodea (Sphingomonas paucimobilis), which is now finding widespread use in food, cosmetics and pharmaceuticals by virtue of its excellent physico-chemical properties. Gellan is a hydrophilic polymer, capable of forming highly viscous shear-thinning dispersions in water. It is also capable of forming hard or soft enteric, mucoadhesive gels in presence of cations. In this work, we have attempted to create a thixotropic suspension of tramadol hydrochloride, which will form mucoadhesive gels in presence of cations in stomach. The suspension was formulated by dispersing calcium citrate, and tramadol hydrochloride in gellan solution. At low pH (simulated gastric fluid), calcium (Ca^{2+}) was released from calcium citrate and induced the gelation of gellan. In in vitro study (in USP dissolution apparatus) maximal release of drug was attained at 7.0 hours comparable to a marketed tramadol SR tablet (7.5 hours). In in vivo study (using albino rabbits) minimum effective plasma concentration was maintained for 6.0 hours (formulation) and 6.2 hours (marketed tramadol SR tablet). Furthermore, the suspension was found to be pharmaceutically elegant, stable with minimal settling and good thixotropy for extended periods of time. Therefore formulation of in-situ gelling suspension, using gellan, of tramadol hydrochloride may provide an interesting avenue for development of a sustained release formulation, which may ensure patient compliance.

AP 16 Screening of the formulation variables on diltiazem hydrochloride release from osmotic pumps

S. Bharath* & Shobha Rani R. Hiremath[1]

* M.S.Ramaiah college of Pharmacy, M.S.R.I.T.Post, Bangalore-54.

1. Al- Ameen College of Pharmacy, Hosur Road, Bangalore – 27.

Osmotic drug delivery system is one of the novel concept in controlled drug delivery used for altering and controlling the absorption, blood levels, metabolism, organ distribution and cellular uptake of pharmacologically active substances. It has found to produce more significant use in pharmacotherapy of cardiovascular diseases.

Thus in the present research objectives was aimed to formulate, optimize and evaluate osmotic regulated delivery of cardiovascular calcium antagonist Diltiazem hydrochloride using an osmotic controlled delivery device asymmetric membrane and also to study the effects of formulation variables on the drug release kinetics .

Asymmetric membrane capsules of cellulose acetate with varied water permeabilities was prepared by phase inversion wet process method using the fabricated manual capsule manufacturing machine. The prepared capsules were subjected to IR spectroscopy and SEM to study the characteristic asymmetric nature of the membrane capsule. The preformulation and compatibility studies of the drug with the osmopolymers PVP, NaCMC, HPC, HPMC and Crospovidone was carried out in different blends and ratios and finally crospovidone and HPMC were selected for further studies.

Two level factorial Plackett-Burmann design was generated with independent factors cellulose acetate,

crospovidone & HPMC and dependent factor of diltiazem- hydrochloride. The designed formulations were subjected to invitro dissolution test to determine the drug release profiles. By applying statistical methods, the influence of capsule shell content and osmopolymers on the drug release was studied and compared. The ratio of mean square variation and residual errors tested by ANOVA resulted the values of "Prob>F" less than 0.02 which indicated the designed model is significant.

AP17 Comparison of skin permeability of drug in shed snake, mice and human cadaver skin

S. G. Gattani*, Prof. R. S. Gaud, Prof. S.C. Chaturvedi*****

Dept. of Pharmacy SGSIT, Indore* AICTE Advisor, NewDelhi**. Vice Chancellor RGTU, Bhopal***

The antihistamine chlorpheniramine maleate (CPM) is used for symptomatic relief of hypersensitive reactions and in pruritic skin disorder and Ondansetron Hcl in the treatment of chemotherapy induced emesis. The objective of the present study was to compare the drug permeation through human cadaver skin (HC), shed snake skin (SSS) & mice skin (MS) with or without penetration enhancer. To investigate potential of CPM and Ondansetron HCl for transdermal drug delivery. Understanding the skin permeability of drugs, their solubility, pKa and log P were determined. Effect of penetration enhancer on solubility was studied. Aqueous solutions of CPM & Ondansetron Hcl at 1% concentrations were prepared drug permeation properties of both drugs studied on HCS. SSS and MS using keshary -chain diffusion cell. Above finding shows that permeability of CPM & Ondansetron HCl from the aqueous solution was low and the flux of the drug was in following order SSS>HCS>MS. Indicating that drug was capable of being transported through the skin. To improve the permeation of drug, we have selected carvacrol, limonene, oleic acid, menthal and mixture of menthol, thymol and camphor as penetration enhancer. The cumulative amount permeated through HCS, SSS and MS was significantly increased. Data analysis was done using steady state flux, permeability coefficient and enhancement ratio. From the study it can be deduced that the steady state is established in all of the tested formulations after about 1-2 h. The limonene & oleic acid was an effective accelerant. The finding provided rational basis for logical selection of alternate membrane to substitute human cadaver skin, which are extremely difficult to obtain. CPM has potential to formulate in TDDS.

AP18 Design of microemulsion based clotrimazole gel.

Mandawgade Sagar D, *Date Abhijit A., Patravale Vandana B.

Pharmaceutical Division, University Institute of Chemical Technology, Matunga, Mumbai -19

Clotrimazole (CLZ), a poorly water soluble imidazole derivative, is locally used in the treatment of fungal infections of skin and vagina caused due to yeasts and dermatophytes. Currently, most of the marketed topical Clotrimazole formulations are presented in the form of creams. These dosage forms have a limited penetration through the *stratum corneum.* Microemulsions are well known for their thermodynamic stability, transparency, excellent solubilizing power and ease of manufacturing. Microemulsions provide reservoir for the drugs thus acting as sustain release vehicles. Also they allow enhanced penetration of the drug by interacting with the lipid bilayers of the skin. Current work was aimed at exploring Microemulsions as a topical drug delivery vehicle so as to achieve optimal localized concentration and prolonged action of the clotrimazole for improved anti-fungal therapy. Components falling in GRAS category were selected for study. Solubility of CLZ in various oils was investigated. Oils that solubilized maximum amount of CLZ were selected for study. Suitable surfactants and co-surfactants were screened for selected oils to yield O/W microemulsions. Microemulsion existence area was determined by constructing pseudo-ternary phase diagram using titration method. Microemulsions were characterized for isotropicity, thermodynamic stability, pH, drug content and rheology. Anti-fungal activity was demonstrated against *C. albicans.*

Various gelling agents were screened for formulation of gels. Gels were characterized for viscosity, clarity, pH, drug content etc. and were subjected to stability testing. Skin irritation studies were performed for Microemulsions and gels. Developed Microemulsion based clotrimazole gel revealed good potential as substitute for existing formulations and can be used for topical as well as vaginal delivery of CLZ.

AP19 Cow ghee (clarified butter) as an innovative agent in controlled release medication

Sakarkar D.M,[1] Shrikhande V. N.,*[1] Vyas J.V.,[1] Jaiswal S B.,[2] Dorle A.K.[3]

1 Vidyabharati College of Pharmacy, C.K. Naidu Marg, Camp, Amravati (M. S.) , Pin- 444602

2 Gurunanak Technical Institute Bezonbagh, Kadbi Chowk, Nagpur (M. S.)

3. Dept. of Pharmaceutical Sciences, Nagpur University Campus, Nagpur (M. S.)

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In the present investigation an attempt was made to examine whether formulation of rifampicin capsules may be achieved with advantages by using fatty excipient as a binder during compaction of rifampicin with other material. Special attention is given to incorporating ancient medicinal formulation excipient. i.e. cow ghee. Result of some recent investigations provide sufficient reasons to believe that ghee obtained from cow's milk can influence the release of some antibiotics from their dosage form formulations, including those for dermatological use. Controlled release formulations of capsule using rifampicin and rifampicin plus isoniazid were prepared. Retardation of release for both formulations with an increase in cow ghee concentration and can be attributed to the fact that hydrophobic nature of cow ghee. Which not just delay dissolution but also prevents rapid wetting of the active ingredients and slowed partitioning of drug from the lipid matrix to the aqueous dissolution medium. In conclusion, among the different strategies employed for the design of a controlled – release capsule dosage form, use of cow ghee as an excipient during compaction of rifampicin and rifampicin plus isoniazid in the formulations seems a promising alternative. It may be possible to employ cow ghee in different combination to develop the controlled – release capsule dosage forms. This new method for controlling release rates of rifampicin. The cow ghee will be an alternative choice for use as an excipient in compaction method to develop controlled – release dosage forms in the near future.

AP20 Design and evaluation of wax coated microcapsules of diclofenac potassium for sustained release

N.H. Indurwade, (Ms) Bhavana Patel*, V.V. Redasani, G.P. Phutane

S.N. Institute of Pharmacy, Pusad 445 204

Diclofenac potassium is a non steroidal anti-inflammatory drug. It has been found to exert a pronounced analgesic effect in moderate and severe pain. The plasma half-life of the drug is 2-2.5 hrs, thus it is the good candidate for the formulation of the sustained release dosage form. In present work the sustained release microcapsules of Diclofenac Potassium were formulated by using waxes. The melt dispersion technique was used to prepare microcapsules. We preferred the use of carnauba wax, stearic acid, stearyl alcohol and beeswax as retardant material because their degradation is independent of pH. Microcapsules in core: coat ratio of 1:2 and 1:4 were formulated. They were analyzed for total drug content. All the five formulations were evaluated for physical properties like particle size, bulk density, and angle of repose.

The size range of various prepared microcapsules was between 96 to 276mm. Average bulk density values are found out to be less than 0.71 g/cm, which indicates good flow characteristics for the microcapsules. Angle of repose for the prepared microcapsules is found out to be less than 40^0 which indicates free flowing properties. Diclofenac showed pH dependent solubility. As the pH of the dissolution medium increases from gastric to intestinal pH the solubility also increases. From the dissolution study it was observed that, the microcapsules prepared with carnauba wax in the core: coat ratio of 1:4 gives better sustained action for about 8 hrs as compared to other formulation.

AP21 Daunorubicin loaded monolithic poly-e-caprolactone microporous microspheres: in-vitro and in-vivo evaluation

Sunil Agrawal*, Srinivas Muthalik, G. Subramanian and N. Udupa

College of Pharmaceutical Sciences, MAHE, Manipal

Injectable microsphere drug delivery system using biodegradable polymers containing various pharmaceuticals has been studied extensively during the past two decades. The objective of this study was to formulate a monolithic microparticulate depot system for daunorubicin employing poly-e-caprolactone as a polymer matrix to suppress tumor growth and to maintain constant plasma drug concentrations within an optimal therapeutic window over a prolonged period of time. The prepared microspheres were evaluated in vitro for physicochemical characteristics, drug release in phosphate buffered saline (pH 7.4) and evaluated in vivo for anti-tumor efficacy along with drug plasma concentrations in tumor (fibrosarcoma) bearing mice. Microspheres were found to be spherical and regular with percent drug entrapment of 68.23 ± 4.28%. This investigation revealed controlled drug release from the formulation and significant suppression of tumor growth kinetics when compared to control upon subcutaneous injection at a dose of 10mg/kg and 20mg/kg body weight. A preliminary pharmacokinetic evaluation exhibited steady plasma drug concentrations during the study period. This formulation with its reduced frequency of administration and better control of drug disposition is expected to provide an economic benefit to the user compared with products currently available for chemotherapy.

AP 22 Studies of ancient formulations excipient and their evaluation on nimesulide suppositories

Sakarkar D. M.,[1] Vyas J. V.,*[1] Shrikhande V. N.,[1] Jaiswal S. B.,[2] Dorle A. K.[3]

1. Vidyabharati College of Pharmacy, Amravati (M. S.), Pin-444 602.
2. Gurunanak Technical Institute Bezonbagh, Nagpur. (M. S.)
3. Dept. of Pharmaceutical Sciences, Nagpur University, Nagpur. (M. S.)

The effect of different suppository bases on in vitro release has been previously described. Generally drug release from different suppository bases depends upon drug solubility in the base, the chemical composition of the base and drug particle size. The drug release from suppository bases is influenced by the presence of other excipients in the formulation and may result in an increase or decrease in the rate of release depending on nature of the base and that of the excipient and its concentration. In the present investigation an attempt was made to formulate nimesulide suppositories using fatty bases. Special approach was given to incorporate ancient medicinal formulations excipient i.e. Cow ghee in combination with bees wax. Some reports described *Melia azadirachta* and *Centrartherum anthelminticum* herbal extract and composition may take the form of cream or ointment base on ghee. The cow ghee was standardized for various quality control parameters for reproducibility in the result. Suppositories of nimesulide were formulated using cow ghee and bees wax in combination (1:1) and cocoa butter alone. The prepared suppositories were evaluated with regards to drug content determination, melting range, in vitro dissolution studies, permeation studies, ease of insertion and stability studies. Combination of 1) Cow ghee & bees wax, and 2) cocoa butter suppositories. Suppositories prepared with Cow ghee in combination with bees wax and cocoa butter plain would be a better choice of treatment in chronic inflammation where sustain release of drug for a longer period of time is desired. Cow ghee can be used as one of the excipient in the suppository formulations in near future.

AP 23 Evaluation of release profile of rofecoxib from different topical preparations and its percutaneous absorption

Tandale P.V., Marina Koland*, Ramana M.V., and Satyanarayan D.

NGSM Institute of Pharm. Sci., 3rd Cross, Vivekanand Road, Nanthoor, Mangalore 575 005

Rofecoxib is a selective cyclooxygenase (COX)-2 inhibitor, which has little or no effect on the COX-1 isoenzyme and it has greater selectivity for COX-2 than other NSAIDs. It acts by blocking COX-2 hence inhibiting prostaglandin synthesis and thereby relieving pain and inflammation. In the present study fifteen (15) semisolid formulations were prepared belonging to gels and ointment categories containing 1% w/w Rofecoxib. Here we have investigated the influence of vehicle composition and the use of various penetration enhancers on the release of Rofecoxib. These preparations included carbopol gels, HPMC (Hydroxy propyl methyl cellulose) gels, PEG (Polyethylene glycol) and oleaginous ointments. The solid dispersions (SD) of Rofecoxib: urea (Rxb: U) (1: 9) and Rofecoxib: b-cyclodextrin (Rxb: b-cd) (1: 2) were also incorporated in some of these preparations. The release of Rofecoxib from these semisolid formulations were evaluated by in vitro diffusion or dialysis methods using artificial membrane. Three (3) formulations were selected on the basis of the best release of drug through cellophane membrane and were further subjected to in vitro permeation studies across human cadaver skin. The composition of these three formulations was such that the first one (F_1) contained Rxb: U SD and dimethyl sulphoxide in carbopol gel base, the second one (F_2) was composed of Rxb: b-cd SD, propylene glycol, ethanol and menthol in carbopol gel base, and the third (F_3) was of ointment base containing isopropyl myristate.

Rofecoxib did not exhibit adequate permeation through skin even after eight hours as compared to its release through the cellophane membrane. This suggests the possibility of a strong affinity of hydrophobic drug to the lipophilic stratum corneum or due to the barrier effect of the latter inspite of using permeation enhancers. However the release of Rofecoxib from these three formulations were in the same order as that from cellophane membrane. When a marketed topical gel of Rofecoxib was subjected to in vitro diffusion studies via cellophane membrane, the results indicated that our formulations were far superior with respect to release. When these formulations were subjected to stability studies there was observed to be no significant difference in various physical characteristics or drug content for duration of four weeks. The results indicated that, amongst the three best formulations, the first formulation (F_1) is a suitable formulation for local delivery of Rofecoxib.

AP 24 Preparation and characterization of different crystalline forms of atenolol to improve its dissolution behavior

S. S. Harale, S.A.Khan and P.G.Yeole*

Institute of Pharmaceutical Education and Research, Wardha- 442 001 (M.S.)

The pharmaceutical approach in overcoming the bioavailability problem involves modification of formulation, manufacturing process or habit modification without changing the chemical structure.

Atenolol, a cardio selective α-blocker widely used in the management of hypertension and angina pectoris is slightly soluble in water and has low bioavailability which makes it a suitable candidate for increase of its release from dosage forms.

In the present investigation attempts have been made to enhance dissolution rate of atenolol by producing polymorphs through altering parameters viz pH, temperature, pressure, agitation and solvent.

Atenolol crystals were prepared using ethanol, acetone and water as the crystallizing solvent and the solutions were than treated under different conditions of temperature (-10°c and room temperature), agitation (70, 100,and 120 shakes per minute) and a pressure (200, 150 and 100 mmHg). Atenolol crystals were also prepared by using buffers of pH 4, pH7 and pH8 at room temperature.

Prepared atenolol crystals and untreated atenolol sample were subjected to dissolution studies and analyzed by UV spectrometer at 223nm.

Increased dissolution rate was found in atenolol crystals obtained from water and ethanol at – 10°C and acetone at room temperature. Dissolution rate was also found to increase in crystals obtained from buffer of pH 4 and pH 7 and moderate increase in dissolution was observed in crystals obtained under pressure of 200mmHg as compared to untreated atenolol.

Crystals with better dissolution rate were subjected to Xray diffraction study and diffractrograms revealed changes in the intensity and locations of peaks in different crystal forms which shows change in crystal habit.

Thus habit modification seems to provide an alternative means to improve dissolution behaviour of drugs.

AP25 Studies on sol-gel transformed systems - an approach to optimise topical ocular drug delivery

Dr. K. Purushotham Rao and S.S. Bushetti*

Lugman College of Pharmacy, Behind P&T Colony, Old Jewargi Road, Gulbarga 585 102, Karnataka

Poor bioavailability of ophthalmic products is due to the dilution and drainage of the drugs from the ophthalmic cavity. Among the various techniques, sol-gel transformation is the technique by which one can improve the bioavailability of drug by increasing residence time. Carbopol-974p solutions 0.3% and 0.4% w/w at pH 4.0 phosphate buffer with and without added hydroxyethyl cellulose (0.3% and 0.4%) were prepared. At pH 4.0, the solutions were of low viscosity and after increasing the pH to 7.4 the solutions became more viscous. The viscosity is measured by using Ostwald's and Brook field viscometer model LVDV-II+. Solutions of 0.3% carbopol at pH 4.0 with and without added hydroxyethyl cellulose were found to be 1.70, 3.25 and 3.62, at pH 7.4 the transformed gels gave values of 14.8, 18.0 and 20.5 cps respectively. Similarly, carbopol solutions of 0.4% at 4.0 pH with and without added hydroxyethyl cellulose were found to be 1.93, 3.91 and 4.38, at pH 7.4 the transformed gels gave the values of 56.8, 75.9 and 76.5 cps respectively. The drug release from the selected gels was studied by dynamic dialysis technique. The release data was treated according to Higuchi's equation $Q=K^{1/2}$ and Peppa's exponential equation $Q=K^{n}$. The kinetic values shows that, the drug diffusion follows fickian diffusion control. Hydroxy ethyl cellulose in the selected concentration added as a viscolizer was found to increase the viscosity and prolong the drug release from the gels.

AP26 Effect of selected solubilization techniques on dissolution profile of nonpolar drug

Sridevi Nayak. M*. Gopkumar. P. and V. Swamy

S.A.C.College of Pharmacy, AIMS campus, B.G.Nagar – 571448. Karnataka, INDIA.

Much variation in the dissolution characteristics of a nonpolar drug rofecoxib was observed when different types of solubilization techniques were included in dissolution media like change in pH of the dissolution media (acidic, neutral, alkaline), addition of co-solvent (20% methanol) and addition of surfactant (1% SLS). ANOVA of dissolution efficiency (DE30) values and Duncan's multiple range test were used to compare the performance of various dissolution enhancers. Based on the DE30 values the order of performance of dissolution enhancers were highly alkaline dissolution media>co-solvent addition> surfactant addition>acidic buffer media>water media>phosphate buffer media.

Study conducted was conclusive in selecting effective and discriminative dissolution media for tested nonpolar drug rofecoxib. Among the different dissolution enhancers selected, increase in pH of dissolution media showed maximum enhancement in dissolution rate. All prepared tablets fulfilled the official requirements for tablets.

AP27 Formulation and evaluation of colon specific matrix tablets containing naproxen

K. Purushotham Rao[1] and C. C. Patil*

B.L.D.E.A's College of Pharmacy, Bijapur 586103, Karnataka.

1. H.K.E.S's College of Pharmacy, Gulbarga 585105, Karnataka.

In recent years there has been considerable research in the field of colonic drug delivery. Oral matrix tablets made of natural or modified polysaccharides were tried for colon-specific drug delivery. These matrices are assumed to remain intact in the physiological environment of stomach and small intestine, but eroded in the colon as a result of degradation by bacterial population of the colon.

The objective of the present research was to formulate and evaluate the matrix tablets of naproxen using a natural polysaccharide, guar gum. The five different tablet formulations were prepared by wet granulation method using starch mucilage as a binder, lactose as diluent and mixture of talc and magnesium stearate as lubricants. Guar gum (10%, 20%, 30%, 40% and 50%) was included in the formulations containing 100 mg of naproxen; tablets were subjected for hardness, drug content uniformity and in vitro drug release study. The in vitro drug release was carried in buffers of pH 1.2 and pH 7.4, using USP dissolution apparatus at 37°C and 100 rpm. Hardness was found to be in the range of 6.0 to 7.0 kg/cm^2, the tablets showed 98.23 % to 99.12 % of the labelled amount of drug indicating uniformity in drug content. The matrix tablets containing 10% guar gum released 6.16 % and 91.80 % of drug at the end of 2nd and 24th hr. whereas; drug release from tablets containing 20%, 30%, 40% and 50% of guar gum was 89.02 %, 79.17 %, 69.28 % and 63.24 % respectively at the end of 24th hr. Drug release from all the formulations followed the diffusion-controlled mechanism (r=0.9162, 0.9182, 0.9046, 0.9073 and 0.9440 for F-I, F-II, F-III, F-IV and F-V formulations respectively). On exposure to dissolution medium, the guar gum gets hydrated and forms a viscous gel layer that decreases the further penetration of fluids into tablets and the hydration of guar gum seems to be independent of the pH of dissolution medium. By increasing the amount of guar gum in the matrix from 10 % to 50 %, the drug release was decreased from 91.80 % to 63.24 %. Lesser amount of drug release from tablets containing 50 % of guar gum may be due to the high gel strength of swollen matrix, which might have prevented the drug release. Thus the matrix tablets containing 10 % and 20 % guar gum are most useful for colon specific delivery of naproxen. Further work is in progress.

AP$_{28}$ Formulation and evaluation of transdermal drug delivery system of verapamil hydrochloride

S.K. Shoo*, S. Chatterjee, R. Pothal, B. Mahanty[1], B.B. Barik

Univ. Dept. of Pharm. Sci., Utkal University., Bhubaneswar.

1. College of Pharm. Sci., Mohuda, Berhampur, Orissa

Verapamil hydrochloride is a calcium channel blocker drug and effective in the treatment of angina, hypertension and arrhythmia. But it is substantially metabolized in the liver when administered orally, showing only 20% bioavailability.

In the present investigation, verapamil hydrochloride is formulated as transdermal patches using ethyl cellulose as polymer to avoid the above problems and to study the effect of penetration enhancers on transdermal permeation of the drug. The patches were prepared on mercury substrate dissolving ethyl cellulose in chloroform and dubiety phthalate included as plasticizer. The penetration enhancers like dimethyl formamide and dimethyl sulfoxide were added in different concentrations.

Films were evaluated for tensile strength, drug content, skin irritation test, weight variation test, flatness test. SEM, FTIR, DSC and in vitro skin permeation test through mice skin were studied. The in–vitro release data were rigorously analyzed in computer. Permeation flux, lag time, diffusion co-efficient, permeation coefficient, partition coefficient and finally permeation enhancement factors were calculated.

Scanning Electron microscope study reveals that the drugs are uniformly coated and distributed throughout the film. In vitro skin permeation study shows that there is increase in permeation as the concentration of permeation enhancer in the film increases. The combination of DMSO, PVP, Ethylcellulose is the best formulation in order to increase the permeation of drug across the biological membrane in a controlled manner.

AP$_{29}$ Improved antibacterial activity of sparfloxacin by formation of inclusion complex with β-cyclodextrin

Sunil Kumar Agrawal, Venkatesh, Srinivas Mutalik, G. Subramanian, Arun Kumar[1] and N. Udupa*

College of Pharmaceutical Sciences, MAHE, Manipal

1. Department of Microbiology, Kasturba Medical College, Manipal 576 119

Sparfloxacin, third generation fluoroquinolone antibiotic is sparingly soluble in water akin to other fluoroquinolones. Sparfloxacin-b-cyclodextrin inclusion complex was prepared by kneading method with an intention to improve the solubility thus anticipating an increased antibacterial activity. 1:1 molar ratio was employed in the study. Formation of the inclusion complex was confirmed by infra red and Raman spectral analysis. In vitro dissolution studies conducted for the plain drug, physical mixture of sparfloxacin and

b-cyclodextrin and inclusion complex indicated a significant improvement in the dissolution rate of the drug from the inclusion complex. Antibacterial study also indicated that the minimum inhibitory concentration of the inclusion complex was much less compared to the plain drug and the physical mixture. Further studies should be carried out to evaluate the effect on the bioavailability of sparfloxacin due to the increase in the solubility obtained by the formation of inclusion complex of the drug with b-cyclodextrin.

AP30 Application of *Moringa oleifera* gum as a suspending agent in the formulation of sulphamethoxazole suspensions

Girija Prasad Patro*, G. Chandra Sekhara Rao, K. Srinivas and M.E.B. Rao

Pharmaceutics Division, Roland Institute of Pharmaceutical Sciences, Berhampur(Gm) – 760 010, ORISSA.

In recent years, plant gums have evoked tremendous interest due to their diverse applications in pharmacy in the formulation of both solid and liquid dosage forms. They are employed as suspending agents in the formulations containing indiffusible materials and as binders in the formulation of tablets. In the present work gum obtained from *Moringa oleifera* was studied as a suspending agent in the formulation of sulphamethoxazole suspensions.

Nine sulphamethoxazole suspensions were prepared employing Moringa gum, Xanthan gum and Sodium carboxymethylcellulose as suspending agents each at three different concentrations. The prepared suspensions were evaluated for viscosity, pH, redispersibility, sedimentation volume and dissolution rate. The pH of the suspensions prepared with Moringa gum was in the range of 3.92-4.46. The viscosity of the Moringa suspensions was 30.72, 71.59, 102.85 cPs for 0.25% w/v, 0.5% w/v and 1% w/v respectively. The sedimentation rate of Moringa suspensions was comparable with the suspensions containing Xanthan gum. The supernatant was cloudy even after one week. Formulations containing Moringa gum exhibited higher dissolution rate followed by the formulations containing Xanthan gum and Sod. CMC. From this results and discussion, Moringa gum was found to be a potential suspending agent in the formulation of suspensions.

AP31 Studies and comparative pharmacokinetic evaluation of rectal suppositories of dilitiazem hydrochloride in rabbits

Sakarkar D. M.,[*1] Shrikhande V. N.,[1] Vyas J.V.,[1] Dorle A. K.,[2] Jaiswal S. B.[3]

1. Vidyabharati college of Pharmacy, C.K. Naidu Marg, Camp, Amravati (M. S.). Pin- 444602
2. Dept. of Pharmaceutical Sciences, Nagpur University Campus, Nagpur (M. S.)
3. Gurunanak Technical Institute Bezonbagh, Kadbi Chowk, Nagpur (M. S.)

The literature survey shows that it undergoes variable and extensive first pass metabolism before entering systemic circulation and varies with species. The recent report shown that liver is considered to be the major organ for dilitiazem biotransformation the extra hepatic organs such as intestine and lungs contribute to the first pass uptake and systemic elimination. In the present investigation an attempt was made to formulate rectal suppositories of dilitiazem hydrochloride by employing cow ghee and bees wax in combination as base. The cow ghee was standardized for the reproducibility in the result for various quality control parameters. The suppositories were evaluated for various parameters like drug content determination, melting range, mechanical strength (hardness), in vitro dissolution and permeation studies. The bioavailability of dilitiazem hydrochloride from rectal suppositories was compared with that of oral administration of same dose of the drug. The study was carried out and various pharmacokinetics parameters were calculated. The maximum serum concentration (C max) and area under the curve (AUC 0-¥) were significantly ($p<0.05$) higher in the case of rectal administration to oral administration. However there was no significant difference in time for peak serum concentration (t max) and elimination half –life (t1/2) for both rectal and oral route . The relative bioavailability of dilitiazem hydrochloride was about 75% greater after rectal administration compared to oral route. This may be due to the avoidance of biotransformation of dilitiazem hydrochloride by liver, intestine and lungs.

AP32 Polystyrene nanoparticles of cefotaxime sodium for improved antibacterial action

S. Sathesh Kumar[1*], A Kottai Muthu[2], R Ravi[1] R. Bino Kingsley[1], R. Hemalatha[1]

1. S.B College of Pharmacy, Sivakasi - 626 130
2. Department of Pharmacy, Annamalai, University, Chidambaram.

Cefotaxime sodium is a third generation cephalosporin antibiotic used in the treatment of various diseases like septicaemia, bactericaemia, respiratory tract infections, gynaecological and obstetrical infections. Development of the drug resistance, one of the problems associated with the chemotherapy of cefotaxime sodium, which may be due to low uptake of the drug by the macrophages or due to development of alternate pathways for protein synthesis. Nanoparticles are one of the recently developed colloidal drug delivery systems having a size range of 1 nm - 1000nm. They have the capability to deliver the drug at an optimum rate at the desired site of action. Cefotaxime sodium is loaded in nanoparticular drug delivery system in order to increase uptake of drug by the macrophages and also reduce the adverse effects of drug.

Cefotaxime loaded polystyrene nanoparticles (CEFNP) were prepared by emulsion polymerization in continuous aqueous phase. Four batches of CEFNP with varying proportions of polystyrene CEFNP-1(1:1) CEFNP-2 (1:2) CEFNP-3 (1:3) and PNP (blank) were prepared and their particles sizes were 300 (±40)nm, 500 (±20)nm, 800(±80)nm and 200(±20)nm respectively. The increase in polymer content caused considerable increase in both particle size and drug content. CFENP-3 exhibited a maximum drug content of 42.2% whereas CFENP-2 and CFENP-1 has 35.7% and 33.7% respectively.

The antimicrobial activities of CEFNP were determined by cup-plate method against standard bacterial strains of *Pseudomonas, E.Coil* and *Klebsella* free cefotaxime sodium and plain polystyrene nanoparticles were aso included for the studies.

The results of these studies indicated that most of CFENP were more active than the free drug. The activity of CEFNP-1 was more against all the three bacterial strains were more when compared CEFNP-3 But the CEFNP-3 had not exhibited any considerable increase in activity against *E.coli* when compared to the free drug. Although the drug content of CEFNP-3. (42.02%) is more, it could not produce considerable increase in the activity. Even though the drug content of CEFNP-1 (33.7%) was low, it exhibited a considerable increase in antibacterial activity. This indicates the size of the particles play a significant in increasing the activity of cefotaxime sodium. This study reveals that nanoparticles can serve as superior drug delivery systems for this drug and similar antibiotics.

AP 33 Formulation and evaluation of timolol bioadhesive ocular gels

Ravichandran, M., Prangya Paramita Pati*, Manikandan, S.R., Praveen Kumar, C.D., Samanta, M.K. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu- 643001.

Timolol maleate incorporated bioadhesive gels were prepared using sodium alginate and the effect of various gel strength 5, 6, 7, 8, 9 and 10% w/v on mucoadhesive strength, drug content and invitro release behavior were studied. All the batches exhibited gel-strength dependent and molecular weight dependent in vitro drug release, which ranged from 2 to 6 hours. A maximum bioadhesion strength of 15.42 (0.6) g/cc was observed in 10% gel. Sterilization by autoclaving followed by testing in microbial culture media established its sterility. Ocular safety studies adopting Draize's test and pharmacodynamic studies in albino rabbits were carried out. Gels showed an initial tear fluid concentration of 5.65 (0.55) ng/µl within 5 minutes. The drug levels were found for about 9 hours in the tear samples. In case of conventional drops no detectable tear drop levels were noted after 10 minutes.The intraocular pressure reducing potential of gel was evaluated in rabbits by tonometric technique and prolonged control of intraocular pressure was for about 8 to 9 hours. It was concluded that the formulated gels containing timolol maleate is superior in maintaining the tear levels and therefore, improve the pharmacotherapy of glaucoma.

AP 34 Formulation and in-vitro evaluation of solid dispersions of aspirin

Vijaya. R* and Ravichandran.V.

Pallavan Pharmacy College, Kanchipuram.

Aspirin, a non - steroidal anti-inflammatory and analgesic drug is poorly soluble in water and in aqueous fluids and its absorption is dissolution rate limited. In order to improve its dissolution rate, solid dispersion systems of aspirin were prepared using citric acid as carrier in different ratios. Fusion method & common solvent methods were followed for the preparation of solid dispersions.

The systems were evaluated for drug-carrier interaction and drug release studies . The studies by TLC revealed that there is no interaction between the drug and carrier molecules. In case of dissolution, the solid dispersions of aspirin showed increased dissolution as the proportion of carrier is increased. So the solid dispersion of aspirin with enhanced dissolution may further increase its therapeutic action.

AP 35 Enhancement of dissolution properties of Itraconazole by solid dispersion technique.

Ashish P. Gorle*, Smt. Rajashree S. M., Ms. Minal R. N.

K.L.E.'s College of Pharmacy, Dept. of Pharmaceutics, Belgaum-10.

Solid dispersion technique has been utilized widely to improve the dissolution of a number of poorly

soluble drugs and thereby their bioavailability. Itraconazole is an orally active antifungal agent, practically insoluble in water and in pH range 1 to 12. In the present study solid dispersion of Itraconazole was prepared using different carriers PVP, HPMC, PEG 6000 in drug carrier ratio of 9 : 1 by solvent evaporation technique. Effect of surfactant tween 20 and SLS 1% w/w in formulation was also studied.

The prepared solid dispersions were subjected to solubility studies in water; 0.1 N HCl (pH 1.2) and phosphate buffer pH 7.4; drug content uniformity; I. R.; X-Ray defraction studies. Based on drug content uniformity studies quantity equivalent to 100 mg Itraconazole was filled in capsule and evaluted for in-vitro dissolution study using USP XXVII apparatus with paddle stirrer at rotation of 70 rpm in 0.1 N HCl at temperature 37 + 1° C. Samples withdrawn at regular interval were analysed spectrophotometrically at 255 nm. In-vitro dissolution study of prepared formulation was studied in comparison with pure drug and marketed formulation.

pH 1.2 was found to show highest solubility of drug. I. R. and X-ray diffraction study revealed that there is no significant change in nature of drug. In-vitro dissolution study in pH 1.2 shows that solid dispersion prepared with HPMC using surfactant SLS released 91.23% of drug as compared to 6.37% of pure drug. Dissolution efficacy showed 12.6-fold increase in dissolution by solid dispersion system as compared to pure drug where as marketed product showed 10-fold increase.

Above studies concluded that HPMC with SLS 1% w/w to be a suitable carrier for solid dispersion of Itraconazole. Solid dispersion techniques can be utilised to increase the solubility and thereby bioavailability of the drug which can be further enhanced by inclusion of surfactant in formulation.

AP$_{36}$ Design and optimization of fast dissolving tablets for promethazine theoclate

Sridevi Nayak. M * P. Gopkumar and V.Swamy

S. A. C. College of Pharmacy, AIMS Campus. B.G.Nagar - 571448. Karnataka, INDIA

Present study comprises about a tablet. Method for making, such which disintegrates or dissolves in a matter of just a few seconds once placed into the oral cavity. In the study fast dissolving tablets of promethazine theoclate were prepared using different fast dissolving technologies. Promethazine theoclate an antihistamic drug and is mainly indicated in cases of motion sickness, nausea, vomiting associated with migraine, and in cases of vomiting associated with traveling etc. Therapeutic use of this drug concluded it to be suitable to place in fast dissolving tablet form.

In the study tablets were formulated using three different fast dissolving technologies like effervescent melt, superdisintegrant addition and melt technology alone. All the prepared formulations were evaluated for various granule and tablet characteristics including dissolution rate. A comparative disintegration time and dissolution rate study indicated the effectiveness of different formulation technologies.

Significant rapid release of drug from the formulated tablets was observed in comparison to the control tablets. All optimized tablets released more than 70% of drug within 10 minutes. Tablets from effervescent melt and superdisintegrant addition technique released 92% and 89% of the drug at the end of 10 minutes respectively. Where as tablets from melt technology released only 71% of drug at the end of 10 minutes even though the tablets were superior in the taste. Study revealed effervcent melt technology and superdisintegrant addition technologies were almost similar in their pattern of drug release. .

In conclusion, it can be said fast dissolving tablets of promethazine theoclate could be prepared successfully. Tablets with added patient benefits and increased consumer satisfaction.

AP$_{37}$ Site-specific mucoadhesive gliadin nanoparticles containing antimicrobial for the clearance of *Helicobacter pylori*

R. B. Umamaheswari*, Siman Ramtake and N. K. Jain

Department of pharmaceutical Sciences, Dr. H.S. Gour University, Sagar 470 003. M.P.

In an effort to improve bioavailability and anti-*H. Pylori* effects of antibiotics, mucoadhesive gliadin nanoparticles (GNP) which have the ability to deliver the antibiotics at the site of infection were prepared. Gliadin was extracted from gluten powder 9 (Wheat flour) and the freeze-dried extracted portion was qualitatively and quantitatively analysed by reversed - phase HPLC (RP-HPLC) and gel electrophoresis method. GNP bearing clarithromycin - (CGNP) was prepared by desolvation method. High drug loading (>50%) was achieved by this process. Increasing the drug : gliadin ratio increased the release rate of drugs. Fluorescein iso thiocyanante (FITC) labelled GNP formulations was prepared with the aim of evaluating their *in-vivo* gastric mucoadhesive property in Mongolian gerbils. Typically, the amount of nanoparticles remained was calculated to be 86%, which represented a strong mucoadhesive propensity and specificity of gliadin nanoparticles towards stomach. In addition, *the vivo* clearence of *H.pylori* following oral administration of the CGNP formulations to infected albino rats was examined. The plain drug and formulations both showed anti - *H pylori* effects in this experimental model of infection, but the required dose for complete eradication were less in formulations than the plain drug. In conclusion, formulations more effectively eradicated the H. Pylori from the gastrointestinal tract than plain drug due to the prolonged gastrointestinal residence time attributed to their mucoadhesion. A dosage form containing mucoadhesive nanoparticles containing antibiotic should be useful for the complete eradication of *H.pylori.*

AP 38 Design of cab microspheres of diclofenac for colon targeting

K. Prakash* , S. Suresh, K. Shanta Kumari, M.E.B. Rao and S.S. Patro,

Roland Institute of Pharmaceutical Sciences, Berhampur-760010, Orissa

Microspheres of diclofenac sodium using cellulose acetate butyrate as coat material were prepared for targeting to colonic region. Non-aqueous emulsion solvent evaporation technique was employed to prepare the microspheres of various core-coat ratios. The microspheres obtained were spherical and free flowing. The in vitro drug release studies have shown that the release rate of diclofenac from microspheres was inversely proportional to increase of the polymer concentration and directly proportional to reducing of microsphere size. The drug release was controlled in acidic medium and a sharp increase in drug release was observed in pH 7.4 medium indicating that cellulose acetate butyrate can be used as coating material for microspheres to control the release in acidic medium. The percentage coating and wall thickness increased proportionally with increase in polymer concentrations of the microspheres. A good linear relationship was obtained between wall thickness and release rate. The drug release followed first order kinetics and was of diffusion controlled. The T90 for core:coat ratio of 5:5 was found to be 5.56 hr. It was concluded that the polymer can be used to retard the drug release from microspheres and it was proposed that higher concentration of polymer is required to extend the drug release for targeting to colonic region.

AP 39 Design and In-vitro evaluation of floating microparticles of nimesulide

G. Sadiq Basha*, P.G. Sunitha, C. Ramasamy, P.E. Venkataramanan

Dept. of Pharmacy, Madras Medical College, Chennai

A novel floating controlled release drug delivery system was formulated in an effort to increase the gastric retention time of the dosage form and to control drug release. The present study involves the design of nimesulide floating microparticles using Eudragit polymers.

The floating microparticles were prepared by coacervation method using the polymers mixture Eudragit S100 (ES 100) and Eudragit RL 100 (ERL 100). The drug-polymer ratio was kept as 1:1. The ratio of polymer mixture ES100 : ERL in three different formulations were 1.5 :0.5 (F-I), 1:1 (F-II) and 0.5:1.5 (F-III).

The prepared floating microparticles were evaluated for IR spectra which proved the absence of any interaction between the drug and polymers. The results of physico-chemical properties showed that F-II having low density, good packing factor and compressibility and optimum angle of repose makes them to float in the medium. SEM studies showed smooth surface for F-II and X-ray diffraction patterns indicates the conversion of crystalline form of pure drug to amorphous form in floating microparticles. The in-vitro release and floating ability was studied by using 0.1M HCl as the medium. The release showed that F-II showed nearly 45% release in 10 hrs. which depicts the prolonged release of drug and the data was treated with mathematical equation such as zero order equation, first order kinetics, Higuchi's diffusion equation ($Q = Kt^{½}$) and Peppas equation ($Q = Kt^{n}$). The mechanism was diffusion controlled and followed first order kinetics. The results of floating ability test showed F-II possesses better floating behaviour when compared to other formulations. So, it can be concluded that FDDS of nimesulide using eudragit polymers would be an ideal approach for sustaining the drug release.

AP 40 Hydrogel as topically controlled delivery system for rofecoxib

Priyanka Arjariya*, Sulekha Bhadra, Suneel Ku. Jain, Shikha Agrawal and G.P. Agrawal

Department of Pharmaceutical Sciences, Dr. H.S. Gour University, Sagar (M.P.)

Gelatin hydrogel was prepared by chemical crosslinking method using glutaraldehyde as a crosslinking agent. In the present study rofecoxib a NSAID was chosen as a model drug. The aim of this study was to prepare and evaluate rofecoxib loaded hydrogel for its local effect. Rofecoxib was loaded into hydrogel at the time of preparation. The solution of rofecoxib in dimethylacetamide was added to gelatin solution before crosslinking. Different formulations of hydrogels were prepared and optimized for the concentration of gelatin and glutaraldehyde. Hydrogel was characterized for swelling ratio, % drug loading and in vitro skin permeation rate. It was observed that increase in the concentration of glutaraldehyde caused decrease in swelling ratio, % drug loading and in vitro skin permeation rate. It was also observed that increase in the concentration of gelatin caused increase in swelling ratio, % drug loading and in vitro skin permeation rate. Drug loaded and unloaded hydrogels had no detectable difference in swelling behaviour. Since hydrogel was prepared for the local effect, its action depends on the amount of drug penetrated into the skin. It was observed that hydrogel with highest concentration of gelatin and lowest concentration of glutaraldehyde exhibited maximum penetration of drug into the skin. Stability studies indicated that hydrogel stored at 4°C was more stable than that stored at 37°C. In vivo studies were performed on albino rats for antiinflammatory and analgesic activity. Drug loaded hydrogels showed better analgesic and antiinflammatory activity in comparison to plain drug solution.

AP41 Formulation and evaluation of lincomycin hydrochloride gel.

S. Pattnaik*, A. Samal, A. Dinda, L. Panigrahi, B.B. Barik.

University Dept. Of Pharmaceutical Sciences, Utkal University, Orissa.

Lincomycin hydrochloride is a systemic antibiotic, active against most common gram positive bacteria and several anaerobic organism. It is available in the market as capsule and injection forms. However, the topical application of the drug at the affected site offers potential advantage of delivering the drug directly to the site of action. In the present investigation various gel formulations were prepared with varying concentrations of polymer and penetration enhancer i.e.Isopropyl Myristate (IPM). Various physico-chemical characteristics of the gel like pH measurement, viscosity, drug content, extrudability, spreadability etc. were studied. The dissolution release profile and skin permeation study were carried out using Keshary Chein Diffusion cell.

From the results it was clearly evident that except 0.5% and 0.75 % of Carbopol 940 all the gel formulations showed good extrudability, homogenecity and spreadability. viscosity of various formulations ranged from 24 to 32.58 cps and they did not prove any skin irritation. The drug content was in the range of 95.2 to 107.8 %, the pH of all the formulations was between pH 5-7, which lies within the normal pH range of the skin. The highest release profile was found in formulation with Carbopol conc 2 % and 10% IPM. The dissolution study and skin permeation study indicated that with increase in permeation enhancer concentration, the release profile, permeation flux, permeability coefficient increases. Thus altering the concentration of Carbopol 940 and IPM, the desired concentration of Lincomycin hydrochloride can be achieved in the systemic circulation.

AP42 Development and validation of HPLC method of analysis of ketorolac, evaluation of stability and anti-inflammatory activity of transdermal drug delivery system

Uma H. Mulimani*, M. S. Nagarsenker

Bombay College of Pharmacy, Kalina, Mumbai-98.

Ketorolac, a potent non-steroidal anti-inflammatory agent is effective and at times superior than opioid analgesics, NSAIDs and combinations at a much lower dose. Acrylate matrix systems with permeation enhancers such as lecithin, sorbitan ester and unsaturated fatty acid have been formulated. A simple, precise and sensitive reverse phase HPLC method has been developed and validated for the determination of ketorolac in its formulation using C18 (300×3.9mm) 5m column with mobile phase methanol:water:glacial acetic acid (54:45:1), the flow rate was 1.5ml/min. and UV detector at 254 nm. The retention time was 7.4 min. Linearity was found for 10-100mcg/ml with a correlation coefficient of 0.99 and percentage recovery was 99.2 % indicating accuracy and reliability of the method. There was no evidence of interference from excipients used in the formulation. The proposed HPLC method is therefore suitable for analyzing the drug from transdermal therapeutic system (TTS). Statistical evaluation of drug content data at $p<0.05$ indicated stability of the matrices at accelerated condition. f_2 factor indicated similarity of dissolution curves between zero and different time points at accelerated condition. Accelerated stability studies of the matrices have shown maximum stability at a temperature less than 40°C. The anti-inflammatory activity of the drug and the transdermal system was assessed using carrageenan induced hind paw edema method in rats. Statistical evaluation at $p<0.05$ indicated no significant difference between oral administration of drug and drug delivery by transdermal system during the period of study. These matrix systems can be potentially developed into rate controlled transdermal drug delivery systems minimizing adverse effects associated with oral administration of NSAIDs.

AP43 Compressed guar gum and xanthan gum hydrophiic matrices: Characterization of drug release mechanisms

S. G. Kumar and T. R. Saini

Department of Pharmacy, S.G.S.I.T.S., Indore.

The present research endeavour was directed towards the development and systematic release kinetics of directly compressed matrices containing either guar gum or xanthan gum or in combinations as a release controlling agents, using a structurally novel antidepressant Venlafaxine hydrochloride as a model drug. A systematic in vitro study was carried for these hydrophilic swellable hydrophilic natural gums using dissolution apparatus (paddle method) at 37°C ± 0.5°C and 50 rpm in distilled water. A combination of guar gum xanthan gum matrices in the ratios of 1:0, 0:1, 1:2, 2:3, 9:1 and 7:3. Of these 9:1 and 7:3 combinations were tried with high gum content with or without 5% high viscosity swelling polymers HPMC K100 M were showed synergistic release retarding effect on drug release. The swelling behavior of hydrophilic natural gums was used to control the release of Venlafaxine hydrocholoride. Neither agitation speed nor drug solubility adds any significant water uptake and swelling, but matrices with the lower proportions of gum produced lesser degree of hydration.

The drug release profile was fit into four models namely zero-order, first-order, Higuchi and Pappas model. All the developed formulations except few fit best in to the Higuchian model with 'r' value ranging from 0.9162 to 0.9980 and others with 'r' value between 0.9912 and 0.9904. From the release kinetics study using Pappas model (Power law expression, $M_t/M¥ = Kt^n$, where K is the kinetic constant and 'n' is the indication of mechanism). The release exponent 'n' value ranging from 0.6847 to 0.8460, which is indicative of non-Fickian release (Anomalous) mechanism. The drug release was characterized using similarity factor (f_2) and Different factor (f_1) using marketed capsule formulation containing coated beads of Venlafaxine hydrochloride. The developed system was found to release the drug upto 18-24 hr with at least 80% release in 12 hr gives the similar release profile as compared to coated beads capsule formulation by f_2 value and can be used as a viable alternative for a expensive coated beads capsule formulations available in market with added advantage of enhanced gastric residence time by swellable matrix system.

AP 44 Applications of artificial neural networks in pharmaceutical research

J. L. Patel*, M. C. Gohel, L. D. Patel

L. M. College of Pharmacy, Ahmedabad-380009.

Artificial Neural Networks (ANNs) are computer systems developed to mimic the operations of the human brain by mathematically modeling its neurophysiological structure (i.e. its nerve cells and the network of interconnections between them). In an ANN, the nerve cells are replaced by computational units called neurons and the strengths of the interconnections are represented by weights. This unique arrangement can therefore attempt to simulate some of the neurological processing ability of the biological brain such as learning and drawing conclusions from experience. The present work was aimed to use ANNs in the formulation development of immediate release pseudo dispersion systems.

The immediate release pseudo dispersion system containing nimesulide were prepared by co-grinding method. The dissolution data of the batches were obtained for analysis. The original outputs for the neural network were the dissolution profile of the capsules. The Trajan Neural Network Simulator (Demo version) was used in the study. This is a window based package, which support numerous types of neural networks along with the fastest state of art training algorithms. The software also gives extensive statistical feedback on each network. The inputs were the amount of solubilizers used in the pseudo dispersion systems and the outputs were the responses of the dissolution profiles.

With regard to input feature selection, the algorithms performed well and give consistent ranking for the importance of the inputs. In case of the $T_{90\text{-}10}$ output release rate parameter, the amount of input variables were classified as the most important.

AP 45 Studies on delayed release system of diclofenac sodium tablets for colon targeting

Ajmal Shareef, R. K. Khar, A. Ahuja and Farhan J. Ahmad

Faculty of Pharmacy, Hamdard University, New Delhi - 62

A novel delivery system for delivering drugs to the colon by selecting a suitable polymer with distinct pH dissolution characteristics has been formulated and evaluated. Dry granulation technique was used to prepare Diclofenac sodium core tablets containing Dicalcium phosphate (DCP) and HPMC K4 M. This core tablet was evaluated for weight variation, content uniformity, hardness and friability. Core tablet contained Diclofenac sodium as model drug, which was spray coated. Inner layer consisted of polymer combination containing HPMC and ethyl cellulose & an outer layer consisted of a pH dependent polymer, cellulose acetate phthalate. The dissolution studies on coated tablets were carried out in USP XXIII dissolution apparatus containing 900 ml of dissolution media i.e. in 0.1 N HCl (pH 1.2) and in 0.05 M phosphate buffer (pH 7.5) maintained at 37 ± 0.5°C at 100 r.p.m. Optimized core tablet showed about 98.6% drug release over a period of 12 hrs. The best-fit release kinetics with highest correlation coefficient was achieved with the Higuchi's plot followed by zero order kinetics. The release profile was studied in phosphate buffer of pH 7.5 after simulated gastric pre-soak for 2 hr in pH 1.2 media. No release was observed for 10 hrs in pH 1.2 and for 4.0 ± 0.5 hr in pH 7.5. The delivery system demonstrated its potential for colonic drug delivery by resisting drug release after a predetermined period, which is greater than small intestinal transit time of a dosage form. No interaction was observed between drug and polymers on the basis of IR studies.

AP 46 Development of bioadhesive-particulate drug delivery system for ocular timolol maleate

Ravichandran, M., Nagasamy Venkatesh, D*, Manikandan, S.R., Geogin, E., Samanta, M.K. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu- 643001.

An attempt to develop a bioadhesive particulate delivery system for timolol maleate was made by

applying the concept of bioadhesion on to drug loaded microspheres with the objective of improving its corneal residence and drug availability. Drug loaded microspheres were prepared by surface cross linking method and the effect of certain process and formulation variables namely, drug to polymer ratio, stirring rate, concentration of crosslinking agent and crosslinking time on the average microsphere size, distribution, drug loading and invitro drug release were studied. An ideal batch of microspheres having a mean size 3.92 microns with 34.21% drug loading was obtained. It was then dispersed into a preformulated 10% w/v sodium alginate gel in the proportion of 1:10 and evaluated for its drug content, musoadhesive strength and invitro drug release. The microsphere dispersed gel exhibited a sustained drug release for about 6 hours and showed mucoadhesion strength of 15.42g. Surface sterilization of the microspheres followed by aseptic dispersion into pre-autoclaved gel was found to be an effective sterilization technique. Draize test in albino rabbits ensured its ocular safety. Pharmacodynamic studies using Schiotz tonometer have ensured the potential of this bioadhesive-particulate delivery system of timolol maleate in controlling the intraocular pressure for prolonged periods, when compared to conventional drops.

AP47 Dissolution rate enhancement of rofecoxib by inclusion complexation

Ravichandran, M., Praveen Kumar, C.D*., Manikandan, S.R, Samanta, M.K. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu- 643001.

Rofecoxib, a methyl sulfonyl phenyl substituted furanone derivative is a nonsteroidal anti-inflammatory agent. It is given generally through oral route and well absorbed from gastrointestinal tract, but its onset of action is low due to its poor aqueous solubility of the drug. An approach was employed to increase the aqueous solubility, by formulating rofecoxib inclusion compounds using beta-cyclodextrin. Five batches were prepared with drug carrier ratio 1:1, 1:2, 1:3, 1:4 and 1:8 by cogrinding technique. All the batches were evaluated for yield, bulk density, angle of repose, compressibility, in vitro dissolution and stability studies. The above evaluations revealed that solid dispersions in the ratio of 1:8 is an ideal batch. The invitro release was compared between bulk drug and formulated inclusion complex, which showed 21.74% and 36.70% respectively in 3 hours. About 24.8% of drug is released within 5 minutes from inclusion complex, whereas bulk drug showed only 3.54% release in 5 minutes, which accounts for 7 times increase in onset of action in inclusion complex. It was concluded that dissolution rate and onset of action of rofecoxib can be improved by inclusion complexation and may enhance the invivo dissolution of the drug.

AP48 Development and characterization of periodontal strips containing complexes of β-cyclodextrin with antimicrobial agent

[a]Narayana Charyulu R*., Saratchandran C., D. Satyanarayana, [b]Shyamala Bhaskaran

a. N.G.S.M.Institute of Pharmaceutical Sciences, Mangalore.

b. Al-Ameen College of Pharmacy, Bangalore.

Dental diseases are considered as a major public health problem throughout the world. Since dental disease may be chronic, long term treatment is often necessary. Periodontal disease is an inflammatory response to the overgrowth of anaerobic organism such as spirochetes and bacteriodes in the sub gingival plaque. Periodontal disease, if unchecked, results in the destruction of the bone and soft tissues supporting the tooth which causes tooth loss. The present investigation is to develop the polymeric strips of chitosan containing Ciprofloxacin - b-Cyclodextrin (CD) complex for local controlled drug delivery into periodontal pocket. The drug β-CD complex was prepared by kneading method with 1:1 molar ratio. The drug β-CD complex was incorporated into chitosan polymer by solution casting method using acetic acid (1%) as casting solvent. Microscopical features reveal that drug b-CD complex was dispersed in polymer matrix. The weight, hardness and tensile strength were found to be 1.05 gm, 362.4gm and 175.8 gm/sq.mm. respectively. UV and IR studies confirmed the absence of any chemical interaction between the drug, β-CD and polymer. In vitro dissolution rate studies were carried out by static dissolution of strips for a period of 24 days. This showed an initial burst release followed by a progressive fall in the release of the drug. The mass balance studies showed the percentage of residual drug content did not deviate by more than 3% from the experimental drug content. All the polymeric strips were found to be stable for a period of 10 weeks.

AP49 Formulation and in-vitro evaluation of fluconazole mucoadhesive tablets

P. Ramkumar*, K. Selvakumar and M. Sreenivasa Reddy

Dept. of Pharmaceutics, College of Pharmaceutical Sciences, MAHE, Manipal 576 104, Karnataka.

Oral candidiasis is predominately caused by *Candida albicans*, and is capable of producing opportunistic infections within the oral cavity when appropriate predisposing factors exist. Fluconazole has

several advantages viz; greater selectivity against fungi, better penetration, resistance to degradation, side effects are quite rare. Hence, oral mucoadhesive tablets (F-1 & F-2) of Fluconazole with polymers Carbopol 934P, HPMC K4M at different amounts is chosen for the present study. Study objectives include, evaluation the formulation characteristics like moisture uptake, content uniformity, in vitro release, mucoadhesive strength, and stability studies. Tablets were prepared by direct compression method. In vitro dissolution studies of the prepared formulations were carried out in Sorenson's buffer, pH 6.2, about 70% of the drug was released from formulation F-1 in 12 hours and 98% of the drug was released from F-2 in 8 hours. In vitro mucoadhesion strength of F-2 was 11.87 ± 0.57 (g). Water absorption capacity of the F-2 formulation was studied by keeping at 82.5% RH for 15 days, showed 2.57% increase in weight, hence manufacturing and storage of these tablets should be carried out under controlled humidity conditions. From F-2, the cumulative percentage of drug released (36%) through porcine buccal mucosa was much lesser, when compared to in vitro drug release(98%), this could be attributed to presence of permeability barrier within the oral mucosa. Stability studies of F-2 at 40 ºC and 75% RH for 12 weeks, showed that 91-94% of the drug remaining at the end of the third month. In vivo studies of F-2 is in progress.

AP 50 Use of subliming material in preparing rapidly saliva soluble compressed tablets

P. Vitta, N.M. Harish, Ranjith, M. Sreenivasa Reddy and S. Pandey*

Department of Pharmaceutics, College of Pharmaceutical Sciences, MAHE, Manipal

Fast dissolving tablets are gaining prominence as new drug delivery systems. These dosage forms dissolve or disintegrate in oral cavity within a minute without the need of water or chewing. These are not only useful in administration of drugs in pediatric and geriatric patients in particular but also in patients suffering from dysphagia, leading to improved patient compliance. Use of superdisintegrants is one of the approaches in preparing this dosage form but mouth feel and swallowability are the major concerns regarding the use of these water insoluble disintegrants. The present study investigates a new, easy and convenient method of preparing compressed tablets, which dissolve rapidly in the mouth, using mannitol with camphor.

Camphor, a subliming material, is removed by sublimation from compressed tablets prepared using various ratios (9:1, 8:2, 7:3, 6:4 and 5:5) of mannitol and camphor to obtain rapid saliva soluble formulation. These compressed tablets were found to be rapidly dissolved within 30 s in saliva in the mouth of human volunteers. The crushing strength of the tablets prepared using a mannitol/camphor ratio of 9:1 has sufficient strength for practical use. No significant difference in either crushing strength or dissolution time in saliva was observed after incorporating the model drug, promethazine into the compressed matrix.

AP 51 Formulation and evaluation of floating drug delivery system for oxcarbazapine

Chandrashekar M., Roopa Karki*, Sreenivasa Reddy M.

College of Pharmaceutical Sciences, MAHE, Manipal-576 119.

Floating drug delivery systems offer a simple and practical approach to achieve increased gastric residence and to modify the drug release profile. Oxcarbazapine is first line drug used in the treatment of most forms of epilepsies and presents compliance problem for long term therapy. Preparing a non disintegrating floating dosage form,which can increase its absorbtion in the stomach facilitates oral delivery of oxcarbamazapine.

Polymers used were HPMC (HPMCK4M and K15M) along with Carbopol 934P,Cross CMC, Guar gum, Eudragit RL and Sodium bicarbonate in combination with calcium carbonate as the gas generating agent. The optimized batches were HPMCK4M and Oxcarbazapine (F_1), HPMCK4M, HPMCK15M:Oxcarbazapine (F_2), HPMCK4M, Carbopol:Oxcarbazapine (F_3), HPMCK4M, Cross CMC:Oxcarbazapine (F_4), HPMCK4M, EudragitRL:Oxcarbazapine (F_5). The drug stability studies were carried out at 40 °C and 75% relative humidity according to ICH guidelines.

The physiochemical properties of different formulations, their buoyancy time and the floating time were within the accepted limits. The in vitro release from the floating dosage forms containing HPMC (high viscosity) and carbopol showed slower release and also integrity of the devices was maintained (12hr.). The percentage release profile was in the order of $F_3>F_2>F_4>F_1>F_5$. The in vitro drug release data was treated with mathematical equation such as zero order equation, first order kinetics equation, Higuchi diffusion equation ($Q=Kt^{1/2}$) and Korsemeyer's equation ($Q=Kt^n$). Formulation showed considerable stability for a time period of three months.

It was concluded that oxcarbazapine was released from the tablets by zero order kinetics. The results indicate that floating dosage forms for oxcarbazapine provides a better option for increasing the bioavailability and reliability for epileptic therapy.

AP 52 Preparation and evaluation of bioadhesive niosomal preparation of timolol maleate

Deepika Aggarwal*, Thiraviam Geetha and Indu Pal Kaur

UIPS Punjba University, Chandigarh 160 014

Timolol maleate (TM) is one of the commonly used drug for the treatment of open angle glaucoma. As systemic absorption of TM may cause respiratory and cardiovascular side effects, it is important to minimize its systemic absorption from the eye and also to target it to the ocular tissues. In the present study, we formulated timolol as a niosomal dispersion based on the premise that latter will be better retained in the eye and will release the drug over a prolonged period of time. Further, the surfactants added for preparation of niosomes may enhance the extent of penetration. However, considering that the dispersion would be washed off from the surface of the eye (due to tear fluid dynamics) after sometime, it was proposed to increase the retention of the preparation, on the eye surface, by incorporation of two different mucoadhesives into the formulation. The influence of these mucoadhesive polymers (carbopol 934Pand chitosan) on the in vitro release and in vivo ocular bioavailability (expressed in terms of physiological effectiveness i.e., lowering of intraocular pressure (IOP)) of the formulation of TM entrapped in niosomes was investigated. The bioadhesive capacity of these polymers was compared based on the mucin-polymer interaction studies. Niosomes of timolol prepared by reverse phase evaporation method showed good entrapment of the drug. Reverse phase evaporation vesicles of timolol (plain REVs) were coated with carbopol and chitoson by incubating the pre-formed vesicles in the polymer solution (0.5%) for 5 min. The in vitro release phase of timolol was significantly extended by the presence of bioadhesive coating, with the chitosan coated REVs showing a longer duration of action. The results are compared with a solution of an equivalent amount of timolol maleate in phosphate buffered saline solution (TMS) and with plain REVs of timolol. Physiological effectiveness of the formulations was evaluated in albino rabbits by measuring the change in intraocular pressure (ÄIOP) using a portable non-contact pneumotonometer. The chitosan coated REVs showed maximum duration of action when compared with Plain REVs and TMS.

AP 53 Reverse engineering as a tool for fast track development of generic formulations

Vishal Koradia* and Arvind K. Bansal

Dept. of Pharmaceutical Technology (Formulations), National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, SAS Nagar, Punjab 160 062.

For Indian pharmaceutical companies generic marketing in US as well as in other countries provides an attractive opportunity for low cost and low risk business experience. This can serve as a launching pad for moving higher in the R & D value chain. The objective of present work was to develop a specific strategy and methodology, which included the decoding of innovator product's quantitative formula, manufacturing process determination, and solid-state characterization of API directly in dosage form. Also solid-state characterization of the API was carried out in four Indian formulations.

Experimental: A tablet formulation of ranitidine hydrochloride, ZantacÒ 75 mg tablets (Pfizer consumer healthcare, US) was selected as innovator's product. Quantitative formula was reached by utilizing principle of differential solubility, from tablet powder. Ranitidine hydrochloride Form I & II were characterized by various microscopic techniques, DSC, FTIR, XRD and results obtained from tablet powder were compared with these results. Particle size measurement of API in tablet was carried out using optical microscope attached with a digital imaging system.

Results and discussion: With method developed, inactive ingredients present in tablet core and coat were identified as well as quantitative formula of inactive ingredients present in tablet core was also calculated. Solid-state characterization studies indicated presence of Form II ranitidine hydrochloride in size range of 5 to 10 mm in innovator's product. Out of four Indian formulations three have showed presence of Form II, while one formulation contains both Form I and Form II. Particle size determination revealed that three Indian formulations contain ranitidine hydrochloride in range of 5 to 10 mm, while particle size range in one formulation is 10-15 mm.

From the results obtained, it can be concluded that methodology developed in the area of reverse engineering is successful in decoding the innovator's formulation and can be of high interest to the generic pharmaceutical industry.

AP 54 Formulation and evaluation of sodium alginate microparticles of methotrexate

B. Arul*, R. Kothai, Philip Jacob, B. Sangameswaran, K. Sureshkumar[1], B. Jayakar

Vinayaka Mission's College of Pharmacy, Salem-8

1. Cherraan's College of Pharmacy, Coimbatore

Bioadhesive sodium alginate microparticles of methotrexate were prepared with the aim to avoid first pass effect and to obtain improved therapeutic efficacy in the treatment of cancer. The microparticles were prepared by glutaraldehyde cross-linking method using various concentrations of sodium alginate (0.25 and

0.5%). The prepared microparticles were evaluated for drug content particle size distribution, stability studies, invitro release studies and compared with marketed tablets. The percentage of entrapment was found to be 59.5 and 48.2 % for the sodium alginate microparticles containing 0.25 and 0.5 % of sodium alginate respectively. Stability studies were carried out at various temperatures (4°C, Room temperature, 45°C and 85% RH) and those indicated that both formulations were stable at 4°C and room temperature. Invitro release studies were carried out in 0.1N Hcl by dialysis method. 55.02 and 49.38 % of drug was released from 0.25 and 0.5 % alginate microparticles respectively after 12 hrs. We concluded that the microparticle formulation of methotrexate showed better sustained action.

AP55 Patient compliant drug delivery system for treating asthma

Prabhu, N. B.*, Wadhwani, A. R., and Amin, P.D

Pharmaceutical Division, Institute of Chemical Technology, University of Mumbai, Mumbai-400019

Development of patient compliant formulations is a major research interest. In the present investigation, an attempt has been made to formulate mouth dissolve dosage forms of oral new class of antiasthmatic agent, Montelukast Sodium, using various combinations of flavours and sweeteners. Montelukast Sodium was mixed in geometric proportions with sweeteners, flavors and other excipients. The use of ion exchange resins as superdisintegrants was explored. The blend after screening was compressed on Cadmach single tablet press machine equipped with 10 mm standard concave punches. Comparative study of superdisintegrant action of ion exchange resin with the existing ones viz., crosscarmellose sodium, sodium starch glycolate and crospovidone was also attempted. The mouth dissolve tablets were evaluated for physical and organoleptic properties, drug content and *in-vitro* drug release. Also *in - vitro* disintegration time and *in-vitro* dispersion time were determined. Mouth dissolve tablets were found to be palatable with an *in-vitro* disintegration time of 30-40 seconds. More than 80% of the drug was released at the end of 30 minutes. Ion exchange resin exhibited a very good superdisintegrant action, this making the formulation cost effective.

AP56 Design and In-vitro evaluation of controlled release parenteral microspheres of leuprolide acetate using biodegradable polymers

Mansi Desai,[1]* Amrita Bajaj,[1] Rajakumari,[1] Preeti Raut .[2]

1. C.U. Shah College of Pharmacy, S.N.D.T Women's University, Mumbai – 400 049. 2 Cipla Ltd., Vikhroli – 400 083.

Injectable microspheres containing leuprolide acetate that would deliver the drug at a zero – order rate over a prolonged period have been developed. This has been achieved by developing microsphere systems using biodegradable polymers, poly lactic glycolic acid coplymer (PLGA), which sustainedly release the drug depending on the biodegradation of the polymer and persistently suppress steriodogenesis following a single injection.

Leuprolide acetate, a hydrophilic drug, was entrapped into PLGA microspheres prepared by In–water drying method using w/o/w emulsion. The basic techniques were designed to increase the viscosities of the inner water phase and w/o emulsion. Under the conditions used, it was possible to entrap the drug in microspheres in the range of 10 – 20 % on the basis of the polymer. PLGA polymer in the ratio 75:25 and 50:50 was synthesized by polymerization – condensation reaction. It was evaluated w.r.t: Solubility in various solvents, Molecular weight by gel permeation chromatography, Intrinsic viscosity by Ostwald Viscometer and Percent residual monomers. The microsphere formulations were evaluated on the basis of entrapment efficiency, % drug loading, drug take–up in the microspheres, particle size distribution and in-vitro release profile.

With this novel microencapsulation technique, microspheres with a high entrapment ratio were obtained. These systems will effectively reduce the required dose due to more continuous receptor hits on the target organs and could improve patient compliance. Thus microsphere systems using biodegradable polymers have been designed for controlled release targeted delivery to attain potent and rational therapy.

AP 57 Preparation and evaluation of directly compressible diluents using combination of starch and dibasic calcium phosphate

Kinnari H. Patel*, M.C. Gohel, L.D. Patel, K.R. Vyas

L. M. College of Pharmacy, Ahmedabad.

Direct compression technique is gaining popularity amongst the pharmaceutical formulators because of high production rate, requirement of fewer processing steps and simplified validation procedure compared to wet granulation. One of important advantage of direct compression method is increased stability for thermolabile and moisture sensitive materials. The success of direct compression is determined by the selection of suitable adjuvants. In present research work, co-processed directly compressible diluents containing starch and dicalcium phosphate (DCP) were developed by using simple physical modification method i.e. - granulation, and evaluated for their functionality.

The use of statistically designed experiments helped in optimizing the composition of co-processed adjuvants. A 3^2 factorial design was used for optimizing the heating temperature and heating time of starch: DCP mixture. The addition of binders improved the functionality of the starch: DCP combination. A 3^2 factorial design was also employed to optimize the amount of polyvinylpyrrolidone and hydroxypropyl methylcellulose as binders. Addition of sodium starch glycolate was tried to balance the disintegration time.

Physical characterization of batches was done by measuring flowability, % compressibility, crushing strength, % friability, disintegration time, particle size distribution, in vitro drug dissolution, etc. Physical characterization of batches showed that the agglomerates were suitable for direct compression.

Starch shows insensitivity to alkaline lubricant (Magnesium stearate) mainly because of presence of fragmenting diluent DCP. The Developed DC diluent allows upto 30% accommodation of poorly compressible model drug, Nimesulide. It also imparts desirable functionality with less cost.

The use of a systematic formulation approach can assist pharmaceutical formulators in developing a functionality adjuvant containing starch, dicalcium phosphate, polyvinylpyrrolidone, hydroxypropyl-methylcellulose, sodium starch glycolate and magnesium stearate.

AP 58 Preparation and characterization of directly compressible diluents using lactose and dibasic calcium phosphate combinations

Krunal R. Vyas*, M.C. Gohel, L.D. Patel, K.H. Patel

L. M. College of Pharmacy, Ahmedabad.

Direct compression technique is gaining popularity amongst the pharmaceutical formulators due to numerous advantages over wet granulation. Very few new DC excipients are introduced in the market in recent years mainly because the existing regulations and guidelines indicate that the novel excipient should be treated as new chemical entity with full toxicological evaluation. Hence, formulation scientists around the world have started working on existing approved adjuvants in newer perspectives. Lactose and dicalcium phosphate (DCP) are widely used excipients having their distinct properties. The combination of both excipients may improve their functional properties using suitable binders. Co-processed directly compressible diluents containing lactose and DCP were developed by using wet granulation and characterized for their functionality.

Lactose and DCP exhibit fragmentation property. When both materials exhibit fragmenting property, the binding capacity of those materials is decreased, hence to improve binding capacity, the material having plastic deformation property should be added. Polyvinylpyrrolidone (PVP K30) exhibit plastic deformation property, hence it was used to improve binding capacity and Aerosil® 200 was used to improve flowability and % yield. A 3^2 factorial design was adopted using different concentrations of PVP K30 and Aerosil® 200 as independent variables. To balance between binding, friability and disintegration, sodium starch glycolate was used as a disintegrant.

Physical characterization of batches was done by measuring flowability, % compressibility, Crushing strength, % friability, disintegration time, particle size distribution, in vitro drug dissolution, etc. Physical characterization of batches showed that the co-processed agglomerates were suitable for direct compression. Lubricant sensitivity and dilution potential studies were carried out.

The use of a systematic formulation approach can assist formulation pharmacists in developing a functionality diluent containing lactose, dicalcium phosphate, PVP, Aerosil, sodium starch glycolate and magnesium stearate.

AP 59 Floating and Drug Release Properties of a Hydrodynamically Balanced Diltiazem Hydrochloride Capsules and Tablets

N.R. Shinde*, Y.L. Patel, P. Sher and A.P. Pawar

B.V.D.U. Poona College of Pharmacy, Erandwane, Pune –411038.

Diltiazem Hydrochloride has high rate of absorption form the duodenal site, medium rate in ileum and low rate of absorption in colon. The prolonged gastric drug release is enabled to trickle over the duodenal site. As compared to capsules the tablets would be more suitable floating dosage form due to its compactness to maintain matrix integrity in swollen state. An attempt was made to formulate Hydrodynamically Balanced Capsules (HBC) and Tablets (HBT) each containing DLT (120mg) using HPMC K4M (67mg), HPMC K15M (67mg) in combination or (135 mg) each alone, lactose (100mg) and sodium bicarbonate (0 & 40 mg). The formulations were evaluated for floating properties. The gastric residence time was determined by gamma scintigraphy technique. Drug release studies were carried out in 0.1N HCl for period of 8 hrs.

Though the HBC and HBT formulations contained same proportion of hydrophilic polymer and soluble additive, the latter was non- floating formulation. Non-effervescent HBTs did not float during 8-hrs study. The swollen floating tablets showed greater matrix integrity and intactness than the floating capsules. The drug release occurred by matrix model. The buoyancy imparting agent in combination with soluble additive, changes the gel properties. The Korsmeyer - Peppas constant 'n' was higher for non-effervescent tablets (> 0.8) as compared to effervescent tablets (˜ 0.5). The HPMC K4M and HPMC K15 M alone at total equal concentrations or in combination showed no significant difference in both floating and drug release properties. Tablets containing same components of floating capsules showed non floating properties. Tablets containing same components of floating capsules showed non floating properties. The inclusion of buoyancy imparting agent in the matrix tablets changes the floating properties of HB solid dosage form and shift drug release from erosion to diffusion mechanism.

AP 60 Preparation and evaluation of polyelectrolyte complexes of PVP and carbopol containing diclofenac sodium

L. Srinivas, K. Hima Sankar, A. Seshasayana and K. V. Ramana Murthy*

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam 530 003.

Polyelectrolyte complexes are association complexes formed by the electrostatic interaction between two oppositely charged particles (e.g. polymer-polymer, polymer-drug, polymer-drug-polymer). The polyelectrolyte complexes formed between a poly acid and poly base are little affected by the pH variation of the dissolution medium. Zero order release kinetics can be obtained with highly swellable polyelectrolyte complexes.

In the present study attempts were made to prepare polyelectrolyte complexes of PVP (poly base) and carbopol (poly acid) into which diclofenac sodium is incorporated and studied for its control release. The complexation was evaluated by pH, conductivity and IR studies. The dried polyelectrolyte complexes were evaluated for various parameters like swellability, micromeritic properties and drug release kinetics. Encouraging results were obtained regarding the use of these polyelectrolyte complexes containing diclofenac sodium for their application as controlled release delivery systems for diclofenac sodium.

The changes in pH and conductivity profiles of carbopol solution upon addition of PVP solution clearly indicated the formation of inter polymer complexes. This was further confirmed by the IR Spectroscopic study. The dried polyelectrolyte complexes possess good flowability and compressibility. These complexes were having good water retaining capacity and swellability. The drug release from these micro particles was uniform and extended for longer duration of time. The complexes made from diclofenac sodium, PVP K90 and Carbopol 934P at a ratio 1:2:2 gave good release. These studies revealed the usefulness of polyelectrolyte complexes as the devices for the development of controlled release dosage forms of diclofenac sodium.

AP 61 Preparation, characterization and evaluation of taste masked complex of cefpodoxime proxetil with ion exchange resins

Akshay Koli*, K.M. Ranch, M.P. Wagh, N.N. Inamdar, C.S. Chauhan,

N.D.M.V.P. Samaj's College of Pharmacy, Gangapur Road, Nasik-2.

The problem of bitter and obnoxious taste of the drugs in pediatric and geriatric formulation is a challenge to the pharmacist in the present world. Cefpodoxime Proxetil is a semi synthetic, extended spectrum third generation cephalosporin, which is mainly indicated in upper and lower respiratory tract infection but the problem is its bitterness. The use of strong and weak ion exchange resins has been done successfully to block the functional group responsible for causing the bitter taste by forming complex between ion exchange resin and the drug. Since Cefpodoxime Proxetil contains amino group, which has

a potential of forming, complex with strong cationic ion exchange resins, hence non-bitter complexes of Cefpodoxime Proxetil were prepared using strong cation exchange resins (Tulsion-344, Tulsion-3434 and Micpol-1061) by Batch Process.

In the present work attempt was made to form different drug resin complexes of different stochimetric ratios. These drug resinate complexes were characterized by DSC and FT-IR spectroscopy. The sample of each of drug resin complex was subjected to sensory evaluation for taste by a panel of five members with respect to bitter taste. The release of the drug from each of the ratio of the drug: resin complex was studied at the pH of mouth (pH 6.7) and also at the gastric pH (1-2) to determine the amount of the drug that would be released during the administration of formulation. The stability of the drug resin complexes was studied by carrying out accelerated stability studies at elevated temperatures.

Amount of the drug released from the drug: resin complex was negligible at salivary pH and maximum cumulative percent drug released at the end of three hours at gastric pH was 88% for drug Tulsion-344 complex (1:3.5). Hence the nature of drug-resinate complex was such that at an average pH of saliva (6.7) it was not able to break but it was enough to be broken down by the hydrochloric acid present in the stomach. Thus drug-resinate complex is absolutely tasteless and stable with no after taste and can be formulated into desired palatable dosage form convenient for pediatric and geriatric patient.

AP62 Development and Characterization of Liposome Based Contrasting Agent for Organs Imaging Diagnostics

Rashmi Jain and S. P. Vyas

Shivaji Nagar, Bhopal, MP

The Liposome based contrasting agent not only subdivided the volume of contrast agent into minicontentment if vesicles but also provide to occupied layer space volume as compare to plain contrast agent. Liposomes borne contrasting agent demonstrated better imaging, specially due to their better retention in stomach. However, the results was not long lasting presumably may be due to distraction of lipid vesicles in harsh acidic environment of stomach, in addition to the activity of lipase enzyme. Moreover, coating of liposomes with mucoadhesive agent offered distinctive advantage via liposomes could trap the contents effectively due to lipodal-polymeric diffusion system. As a result, the retention into the stomach was even upto 8h. This property in particular provided for better periodic assistant of identified loci of defects. Additionally, intestine as such is not exposed directly to the higher concentration of contrast agent and the possibility of gastric irritation, or constipation associated with plain solution administration could be obvetiated. The imaging of liver for its size and histology could be made as vesicular system on systemic administration sequestered and textured by RES system of liver causing release of vesicular contents and clearance by organs i.e. liver and spleen. It is also observed that coating of liposomes resulted into better storage stability, which attests this system with workable clinical diagnostic modalities. It could be summed up that liposomes hold great potential as contrast carrier system in imaging diagnostics such as chemiluminence photoirradiated determination (isotope). However, there is a need of systemic studies and evaluation of developed system with individual contrasting / imaging agent.

AP63 Oral controlled drug delivery system using blend of HPMC based gastro-retentive and enteric polymer

A. Rengudwar, R. Dhumal, P.Sher* and A.P. Pawar

B.V.D.U. Poona College of Pharmacy, Erandwane, Pune - 411038

The CDDS due to exposure to different GI environments shows variation in drug absorption or drug degradation. The reduced bioavailability of drug from CDDS was reported to due its entry in lower GIT. HPMC showed higher drug release at lower pH. The gastric retention of dosage form using HPMC plus use of enteric polymer is an alternative to achieve controlled and complete drug release both in upper and lower GIT.. The present study involves design and evaluation of once daily matrix tablets containing theophylline as model drug.

The matrix tablets each containing 400mg theophylline, 120 mg lactose and various levels of HPMC, sodium bicarbonate (SB) and Eudragit R 100 were prepared using KBr hydraulic press. The tablets were evaluated for water uptake, buoyancy lag time, matrix integrity and floating period. The effect of buffer media and pH on floating and drug release was performed using HCl buffer of pH 1.2, phosphate buffer of pH 5, 6.6 and borate buffer of pH 7.5.

The tablet containing SB showed floating with BLT of 8-20 min. and remained floated for more than 8 hours. The higher gel strength in HPMC-2 batch is attributed to 'n' value of 0.5; the n value of HPMC-1 containing higher soluble additives was 0.19. Higher drug release was observed at pH 1.2 than at pH 5 and pH 6.6. The drug release in phosphate buffer and borate buffer was almost same. The water uptake of HPMC matrices was slower in acidic media than in phosphate buffer. HPMC-E formulation contained enteric polymer remained float for 8 hours and counteracted higher drug release from HPMC in acidic media with complete drug release in lower GIT.

The once daily formulation based on blend of HPMC with enteric polymer would be an alternative both for gastro-retention of dosage form and for complete release in lower GIT.

AP64 Comparative evaluation of microcrystalline cellulose prepared from sisal fiber as a tablet excipient

Nitin Bhimte[1], K.M. Paralikar[2], Gopal Hadge[2], Pralhad Tayade*[3]

1. The Bombay College of Pharmacy, Santacruz (E), Mumbai 400 098.
2. Central Institute for Research on Cotton Technology, Mumbai 400 019.
3. University Institute of Chemical Technology, Mumbai 400 019

Microcrystalline cellulose (MCC) is frequently employed as a self compressed vehicle. It has been also included in various tablet formulations as excipient, as a binder and disintegrant. Various methods have been reported to prepare MCC from absorbent cotton and many cellulosic fibres but the experimental data for its use as tablet excipient or as a tablet disintegrant is scanty. In the present study, therefore an attempt has been made to evaluate the MCC prepared from the natural cellulosic fiber (Sisal fiber) and examination of its feasibility as tablet excipient (diluent as well as disintegrant) in comparison to the other products available in local as well as international market. The powders were studied for their moisture content, bulk density, tapped density, true density, angle of repose, flow rate, cohesion and flowability (Carr's method), degree of polymerization, intrinsic viscosity, scanning electron microscopy. Tablets were prepared using Captopril as model drug for each of the microcrystalline cellulose and were evaluated for diluent and disintegrant properties in terms of tablet hardness, thickness, friability, disintegration and dissolution profiles. The developed formulations were compared with existing marketed formulations. No significant difference was found in the packing and tabletting properties of the microcrystalline cellulose samples while utilizing it as wet granulation vehicle.

AP65 Viscosity of PVA membrane and biological membrane through diffusion studies

S. G. Kollyote*, Abha Doshi, U.B. Hadkar

Mumbai Educational Trust's Institute of Pharmacy, Gen. Arun Kumar Vaidya Marg, Bandra Reclamation, Bandra (W), Mumbai - 50

Diffusion of drugs Linezolid and Amoxycillin trihydrate through Polyvinyl alcohol (PVA) and biological membrane was studied at 37° C using Valia-Chein diffusion cell. Linezolid & Amoxycillin trihydrate are having anti-bacterial, antibiotic activity. The PVA membrane was prepared using 2% solution of hot water soluble PVA. The biological membrane used was prepared by cutting the frog's stomach into circular shape to fit neatly at the junction of the receptor and donor compartments. The diffusion data was used to calculate the diffusion coefficient of the drug in the membrane using Tumara-Mizuho equation. The diffusion coefficient so determined was used to calculate the viscosity of the membrane at 37° C using Stokes-Einstein equation namely, $D = KT/3\pi hd$; Where D = Diffusion coefficient, K=Boltzmann constant, T=Absolute temperature, h=Viscosity, d=Particle diameter.

AP66 Ciprofloxacin – loaded poly (lactide-co-glycolide) nanoparticles: preparation and characterization

Praveen. S* and Shobha Rani. R. H

Dept of Pharmaceutics, Al-Ameen College of Pharmacy, Hosur Road, Bangalore – 560 027.

The efficacy of Ciprofloxacin has led to its use being proposed for the treatment of various bacterial diseases. It is effective against Gram-positive and Gram-negative bacterial species. However, Ciprofloxacin is considered to be less effective than other higher fluoroquinolones in the treatment of intracellular infections infecting the macrophages. This has been attributed to its relatively low intracellular penetration and short intracellular residence time. Colloidal drug carriers such as nanoparticles can target to the macrophages, increase intracellular penetration and residence and thus provide better therapeutic efficiency. In this study, the possibility of using Poly (lactide-co-glycolide) (PLGA) nanoparticles as colloidal drug carriers for Ciprofloxacin was investigated. The influence of preparation variables on the loading capacity of PLGA was studied and optimized by a central composite design (CCD). The nanoparticle recovery, morphology, drug content and in-vitro release profile was also evaluated. Optimization studies resulted in identifying the important variables and obtaining preparations, which had maximum drug incorporation. The morphology studies showed spherical discreet particles in the nano size range, which had a drug content of 88% and an in-vitro release of 16% at the end of 12 hours.

AP 67 Design and evaluation of kokum butter baby oil

S.S.Kadam, K.N.Gujar, Sujata, N. Nilakhe*, Padmawar, M.N.

B.V.'s Institute of Pharmacy, Erandwane, Poud Road, Pune 411 038 M.S.

Kokum butter I.P. is solid fat extracted from seeds of Garcinia indica (Guttiferae), used as moisturizer. Present study characterizes Kokum butter by XRD, TLC& DTA. Study also includes purification of Kokum butter, studies on hygroscopicity, autoxidation, formulation dvpt. & evaluation of moisturizing efficacy

Experimental - Kokum butter was analyzed according to I.P. Since it was far below the purity various methods tried for its purification & decolorization. Hygroscopicity was studied at RH between 52%-98% for 21 days. Autoxidation was studied for fat kept in open containers and by peroxide value determination for 21 days. Fat was stabilized using BHT trying various concentrations.

Formulations were developed using olive oil, sesame oil, and cod liver oil and liquid paraffin as vehicles. Moisturizer liquid formulation containing 10.4 % and 7.6% Kokum butter in sesame and cod-liver oil containing 0.013% BHT was prepared.

Moisturizing efficacy of above products was studied using rabbit skin applied with two samples using specially fabricated diffusion cell at different RH and five human volunteers using miniature desiccators with silica gel inside. The wet loss in fabricated cell for rabbit skin and wet gain by silica gel for human volunteers were evaluation parameters for TEWL.

Purification using absolute alcohol and fuller's earth was found satisfactory. Fat found to be hygroscopic. Moisture uptake increased with increase in RH and remains constant as fat saturated. Kokum butter under goes auto-oxidation and stabilized by 0.013% BHT. Both formulations showed moisturizing property. The net increase in TEWL greater by Kokum butter with sesame oil than with cod-liver oil.

Above results are beneficial as skin miniaturization is concerned which takes place by increasing TEWL. The kokum butter will be promising moisturizer in future.

AP 68 Comparative study of tablets containing ibuprofen, paracetamol with and without caffeine for its disintegration and hardness

Manish Dudhani[1]*, V.S. Dattamurthy[2], Suresh Venkataram[3]

1 & 2 JSS College of Pharmacy, Mysore-15
3 Zydus Cadilla Health Care ltd, Bangalore-4

Tablets are the most prevalent dosage form in pharmacy. Physical properties pf tablets such as disintegration time, hardness, are important part as their chemical attributes. The current work involved the formulation of a combination of Ibuprofen, Paracetamol, and Caffeine in form of a tablet. Influences of formulation ingredients such as binders, disintegrants, and the manufacturing process changes on tablet properties were studied. Formulations were prepared, packed by method commonly practiced in the industry and stored under ICH stability conditions for Zone IV. Influence of compression force on hardness and disintegration time for formulations with and without caffeine was examined. Addition of Caffeine did not show any changes in physical properties of the tablet. Changes in the binding agents resulted in difference in disintegration time immediately after compression and also on incubation at accelerated stability condition. Tablets are the most prevalent dosage form in pharmacy. Physical properties of tablets such as disintegration time, hardness, are important part as their chemical attributes. The current work involved the formulation of a combination of Ibuprofen, Paracetamol, and Caffeine in form of a tablet. Influences of formulation ingredients such as binders, disintegrants, and the manufacturing process changes on tablet properties were studied. Formulations were prepared, packed by method commonly practiced in the industry and stored under ICH stability conditions for Zone IV. Influence of compression force on hardness and disintegration time for formulations with and without caffeine was examined. Addition of Caffeine did not show any changes in physical properties of the tablet. Changes in the binding agents resulted in difference in disintegration time immediately after compression and also on incubation at accelerated stability condition.

AP 69 Design and evaluation of pediatric paracetamol suppositories

Ranjita S. Shegokar*, K.K.Singh

C.U.Shah College of Pharmacy, S.N.D.T. Women's University, Santacruz (W), Mumbai- 49

Pediatric Paracetamol suppositories were prepared using different types of semisynthetic glycerides. Amphiphilic base (e.g. Suppocire CP) esterified base (e.g. Suppocire NCX) and interesterified bases (e.g. Suppocire C and D) were used for the formulation of suppositories. Suppositories were evaluated for appearance, surface area, melting point, disintegration time, uniformity of weight, uniformity of drug content and in- vitro drug release.

Effect of various surfactants like sodium lauryl sulphate (0.5, 1%), dioctyl sulphosuccinate (0.5, 1%), Labrasol (2, 5%), Miglyol (10%), Lecithin (1%), Aerosil (1, 2 %), Capryol PGMC (2, 5%), and Span 80 (2%) were studied on the drug release characteristics as well as physical and chemical properties of the suppositories.

Drug was analyzed by using UV spectrophotometer at wavelength 243 nm. Suppositories were evaluated for stability as per ICH guidelines. The type of suppository base and the type of surface-active agent incorporated had definite effect on drug release from suppositories. Suppocire CP (amphiphilic base) and Suppocire NCX (esterified base) showed better drug release as compared to suppositories prepared from Suppocire Cand D (interesterified bases). Out of all surface-active agents Labrasol and Capryol PGMC shows maximum enhancement of drug release from suppositories.

AP$_{70}$ Once daily sustained release cefadroxil formulation

Chaudhari S. V., Sonaje G. R.* and Vavia P. R.

Pharmaceutical Division, University Institute of Chemical Technology, Matunga, MUMBAI – 400 019.

Cefadroxil is one of the commonly prescribed oral cephalosporins. Short half life (about 1.2 hr.), good oral bioavailability, broad spectrum antibacterial activity and higher urinary excretion (93%) justifies the rationale for its once daily formulation. In the present study the drug is released rapidly initially (burst effect) and then small amount of drug is released to maintain the effective concentrations for longer time.

Sustained release tablets were formulated with the objective of releasing about 45% to 50% of the drug in 4 hours and rest of the drug in remaining 20 hours. Sustained release tablets were formulated using hydroxypropyl methyl cellulose (HPMC), ethyl cellulose (EC) and Eudragit L 100 as release retardant polymers. Different combinations of release retardant polymers were used. Tablets were prepared by wet granulation using polvinlprrolidone (5% w/v in isopropyl alcohol) and in-vitro drug release was studied using pH change method. Drug release was quantified using UV-spectrophotometry. HPMC K100M showed sustained release effect in concentration 12% w/w for 24 hours. While HPMC K100M: EC in the ratio 6:1W/W and HPMC K100M: Eudragit L 100 in the ratio 4:6 W/W showed 24 hour release. All the optimized formulations exhibited Higuchi kinetics.

AP$_{71}$ Development and evaluation of oral osmotic systems of metformin hydrochloride

***V.Mohan[1] C. Ramasamy[1], K. Dhyeenasweran[2]**

1. Department of Pharmaceutics, Madras Medical College
2. Medical Stores Organization, Chennai – 3.

'Oral Osmotic System' is the much-hyped term used in the field of controlled drug delivery system. They are being attempted to achieve a controlled zero order release of the drug. Sustained release form of Metformin has an advantage to reduce the dosage frequency which further increases patient compliance and act as a Hypoglycaemic.

Presentation is based on the sustained release form of Metformin, using the principle of Osmosis.

- Preparation of osmotic tablets are carried out and the methodology involved are show cased below.

  Four formulations were developed out of which three were developed by using osmogen in varying proportions (i.e,) 5%, 10%, 15% sodium chloride.
- Preparation of coated tablets using cellulose acetate (2%w/v)
- Orifice formation using laser in various sizes (0.2mm, 0.4mm, 0.8mm, 1.6mm).
- Physiochemical evaluation of coated and uncoated tablets.

AP$_{72}$ Stability studies on felodipine tablets in different blister packaging films

H.G. Shivakumar* and Teena K. Thomas

Dept. of Pharmaceutics, JSS College of Pharmacy, Bannimantap 'B', S.S. Nagar, Mysore 570 015

Felodipine, a vascular selective calcium antagonist, is available as extended release tablet dosage form in three different strengths (2.5mg, 5.0mg, 10.0mg). Felodipine, a research product of Astrazeneca, is marketed in India as extended release tablet dosage form in aluminium /aluminium strip pack. In order to make the pack more patient friendly and cost effective it was proposed to study and evaluate Felodipine tablets in blister packs using different blister films. Different batches of Felodipine extended release tablets of all strengths (2.5mg – 2batchs, 5.0mg – 3 batch, 10.0mg –2batch) were collected and packed in different blister films supplied by different vendors. The blister packed tablets were kept at 40°C/75% RH and analyzed for a period of 6 months for the following parameters viz. appearance, moisture content, dissolution, assay. There was no change in the appearance of the tablets. The moisture analysis using Karl Fischer Titration revealed that there is an increase in the moisture content. The dissolution studies were carried out at initial and after 6 months using USP dissolution apparatus Type II, with a specially made quadrangular basket of gauze wire. The samples were withdrawn at 1st ,4th, 7th hour and analyzed by UV method. It was observed that all the results are well within the limits. The assay results obtained by UV method (Initial, 1st, 2nd, 3rd month) and by HPLC method (at the 6th month) shows that percentage drug content are within the acceptance criteria. Based on the results obtained from the accelerated stability evaluation, blister packaging may be considered as an alternative to strip pack.

AP 73 Preparation and characterization of pH sensitive hydrogels of poly(acrylamide-co-methacrylic acid) as drug delivery system

C.S. Satish*, H.G. Shivakumar

Dept. of Pharmaceutics, JSS College of Pharmacy, Bannimantap 'B', S.S. Nagar, Mysore 570 015

Poly(acrylamide-co-methacrylic acid) hydrogels owing to the existence of hydrophilic COOH and NH_2 groups has the capacity to absorb large amounts of water. The polyacidic polymer will be unswollen at low pH, since the acidic groups will be protonated and unionized. With increasing pH, the polyacid polymer will swell due to electrostatic repulsion due to ionized COOH groups. The opposite will hold good for the polybasic polymer. Poly(acrylamide-co-methacrylic acid) hydrogels were prepared by free radical polymerization. Cross linking agent used was N,N-Methylene-bisacrylamide and potassium persulphate was used as initiator. Acrylamide (AM) and Methacrylic acid (MAA) were used in three different molar ratios 1:0.5,1:1 and 1:2 (F1, F2, F3 respectively). Indomethacin was used as model drug to study the drug release characteristics of the hydrogel.

The prepared hydrogels were then characterized by FTIR. Swelling studies and in vitro dissolution studies were carried out. The swelling studies showed that the swelling increases with increasing concentration of methacrylic acid. Hydrogel with AM: MAA ratio of 1:2 showed 2992% of swelling after 12 hours. Formulation F1 showed 98% release in 12 hours, F2 97% release in 10 hours while F3 showed 100% release in 10 hours. The data obtained were fitted to various models. The best-fit model was found to be Koresmeyer-Peppas model. The n value calculated from the Korsmeyer-Peppas model was >0.5 indicating non-fickian release mechanism. Formulation F1 confirmed with USP XXIII drug release test-2 requirement of indomethacin extended release capsules.

AP 74 Formulation development and evaluation of a multimineral veterinary suspension

R. Kowsalya[1], M. Sree Rama Murthy[2], P. K. Karar[3], S. Sathesh Kumar[1], A. Kottaimuthu[3].

1. Department of Pharmaceutics, S. B. College of Pharmacy, Sivakasi.
2. TTK Healthcare Limited, Chennai.
3. Institute of Pharmaceutical Technology, Annamalai University.

Minerals are chemical elements, which are necessary for the proper functioning and maintenance of vital processes in the body of the human beings as well as animals. Insoluble minerals are formulated as suspensions. Since it is economical to give as much high concentration of minerals as possible in a liquid mineral supplement and essential to compete with the powder mineral supplement available in the market, a multimineral suspension containing very high concentration of minerals for animal use was planned. Because of very high concentration of minerals in the formulation there may be a chance of precipitation or crystal formation. In order to avoid the above two problems, preformulation work was carried out before developing the formulation trials. It indicated that the precipitate was not observed at low concentration of preservatives and in the excess of water. Based on the results of the preformulation work, formulation that did not have any precipitation problem or subsequent crystallization was developed.

Different trials were made by slightly altering the concentration of the excipients. Each trial sample was subjected for physico-chemical evaluation and microbiological evaluation immediately after the preparation and the required modifications were made in the subsequent trials. Among these, fifth trial was satisfactory in all respects and was further evaluated for the parameters such as preservative efficacy test, particle size analysis, mineral content and stability studies. In the preservative efficacy test, the effectiveness of the antimicrobial preservatives present in the formulation was tested against Candida albicans, Aspergillus niger, Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus. This result indicated that preservatives included in the formulation were effective against all the tested microorganisms. Reduction of microorganisms was observed and at the end of 4 weeks no count was observed. Particle size analysis indicated that the maximum particles were within the size range of 20 to 60 microns. Mineral Content evaluation indicated that all minerals included in the trial sample were within the limits of 95 to 105%. During stability studies physico – chemical parameters, particle size analysis and mineral content were evaluated for every 15 days upto 45 days. It showed that suspension was stable during the stability periods.

AP 75 Preparation and evaluation of a nimesulide salt – nimesulide sodium

Sachin W. Lohe.[1] *Rajendra S. Chopade.[2] J.G. Awari.[2]

1. Anurag College of Pharmacy, Warathi, Bhandara 441905
2. University department of Pharmaceutical sciences, Nagpur University, Nagpur 440010.

Nimesulide, chemically 4-nitro-2-phenoxy-methanesulphanilamide is non-steroidal anti-

inflammatory drug, which acts by selectively inhibiting cyclo-oxygenase2. Nimesulide is available in various doses forms, but due to its very poor solubility in water it's oral absorption and dissolution rate is limited. The attempts have been made from time to time to prepare and evaluate new derivatives of nimesulide with improved solubility and bioavaibility as compared to nimesulide.

In the present study a new water-soluble derivative of Nimesulide- sodium had been prepared and evaluated. The prepared salt was formulated in injection form and activity is compared with that of the orally administered nimesulide.

The Nimesulide sodium is prepared by reacting stiochometric quantity of nimesulide with sodium hydroxide in methanol. The derivative was recovered by salting out. IR, NMR and Mass spectroscopy analyzed the prepared derivative. The biological study for the new derivatives includes its anti-inflammatory potential and plasma level concentration studies.

The anti-inflammatory activity of nimesulide and salt synthesized was calculated using formula

% Inhibition of odema = [Vc- Vt]/Vc C 100

Vc= Avg. increase in paw vol. of carageenan injected control animals.

Vt =Avg increase in paw vol.of carageenan injected drug treated animals.

The plasma level of drugs given orally and parenterally compared by isocratic HPLC system consisting of UV detector focused at 230 nm with c18 bond pack 30 cm) reversed phase column.

AP$_{76}$ Formulation and evaluation of bitterless rapidly disintegrating tablet of famotidine using ion exchange resin

Mamta Mishra, Ruchir Umalkar*, Mangesh Bhalekar, Jasmine Avari

Dept. of Pharmaceutical Science, Nagpur University Campus, Amravati Road, Nagpur 440 033

Due to decline in the swallowing ability, many elderly patients have difficulty to take medication in the form of conventional tablets. In the present study the rapidly disintegrating or dissolving tablet of Famotidine has been developed. The problem of bitter taste of Famotidine was masked by using weak acid cation exchange resin like, Indion-234. This particular resin was selected because it has both taste masking and tablet disintegrating properties. The tablet was formulated by direct compression method. The drug resin complex was prepared by taking known amount of the drug and varying amount of the resin i.e. 1:1, 1:2, 1:2.5 and 1:3. The result showed that the drug resin in the ratio of 1:2 has better loading. The effect of pH on loading was also studied and the maximum loading was seen at pH 4.5. The developed tablets were subjected to evaluation for the various parameters like tablet tensile strength, disintegration time, friability, in-vivo disintegration time, in vitro dissolution study, taste, weight variation, content uniformity, X-ray diffraction studies and stability.

The dissolution study of Famotidine tablet showed that more than 80% of the drug was released in 15 min. This formulated tablet then compared with marketed tablet for disintegration time. The result showed that the formulated tablet was disintegrated within 7-10 sec. as compared to 60 sec. for marketed Nimulid-MD tablet (Panacea Bio-tech).

From this it was concluded that the formulated tablet of Famotidine posseses good stability which was bitterless with rapidly disintegrating property.

AP$_{77}$ Optimization of compression binding of layers in sustained release layered tablets

Parita Parekh*, Shajahan A, Poddar S.S.

Principal K.M. Kundani College of Pharmacy, Mumbai.

The release of a drug from a monolithic matrix is inherently non-linear. To overcome this, Multi-layered tablet system has been attempted to provide a zero-order release rate. A three-layered tablet system was constructed having a hydrophobic matrix layer (Diltiazem + Wax + Lactose) sandwiched between two hydrophillic layers (HPMC + Lactose). Layered tablets are known for separation during handling, dissolution and storage. This problem very serious when the layers are hydrophobic and hydrophillic. The objective of this work was to optimize binding between hydrophillic and hydrophobic layers in a multi layered tablet.

In order to achieve this, wax composition, concentration and granules size were optimized for hydrophobic layer to produce 6 hrs release associated with rate which was distinctly of falling type. The hydrophillic layers composition, amount, and the granulating liquid (water:IPA) composition and its amount, granules size, hardness of matrix layer as well as hardness of compressed tri-layered tablets were determined.

The evaluation of layer bondage was carried out using Optical Microscopy of fractured/sectioned tablet surface at 100X., friability and dissolution tests.

The core and coat granules in the size range of 800 µm, coat granule strength obtained by water:Alcohol ratio of 25:75 as granulator and tablet hardness of 6 kg/cm^2 were optimized to ensure adequate layer bondage and release profile.

AP78 Effect of tablet surface area / volume on drug release from guar gum matrix tablet

Vinita Kale, Rahul Kasliwal, Dharmendra Maurya*, Dr. Jasmine Avari

Dept. of Pharmaceutical Science, Nagpur University Campus, Amravati Road, Nagpur 440 033

The objective of this study was to investigate the influence of surface area / volume (SA/ vol) on drug release from sustained release matrix tablet containing guar gum. Soluble drug (Metformin HCl) and insoluble drug (Ibuprofen) were utilized in this study. Drug release mechanism from guar gum matrix tablets were also evaluated. Effect of increasing SA/ Vol (by keeping diameter constant (13 mm) and varying weight of tablet) on release of both the model drugs were examined. Similarly effect of constant surface area on release of drugs (only diameter varied, 11 mm and 13 mm) were evaluated.

Overall tablets with larger SA/vol values had slow release of drug. Whereas no much change in the release of drug was observed related to constant surface area only by changing the tablet diameter. The release showed that SA/vol had greater impact on release from guar gum matrices than tablet surface area.

Release profile for both the drugs when fitted into Higuchi equation for model drugs, it was observed that the release mechanism was predominantly by diffusion.

AP79 Sustained release of flurbiprofen from eudragit solid dispersions

Magar M.D.*, Navhat S.D., Kamble R.K. and Anantwar S.P.

* N.D.M.V.P. Samaj's college of pharmacy, Gangapur Road, Nashik-422002.

Flurbiprofen is an effective non-steroidal anti-inflammatory drug (NSAID), used in the symptomatic treatment of rheumatoid arthritis, osteoarthritis, anky losing spondylitis and acute gouty arthritis. The most adverse side effects occurring with flurbiprofen are gastrointestinal disturbances, peptic ulceration and gastrointestinal bleeding. Hence there is a potential need for sustained release of drug to minimize gastric erosion and other side effects. Its biological half-life on the other hand is very short, sustaining its anti-inflammatory activity only for a few hours. Therefore, there is a need for a sustained release dosage form to prolong the duration of action. In the present study, solid dispersions of flurbiprofen with Eudragit RL 100 and Eudragit RS 100 were prepared and evaluated. Drug release from these polymers is pH independent. These polymers are capable of swelling. Eudragit RS 100 is less permeable to gastric juice and Eudragit RL 100 is more due to its lower content of quaternary ammonium functions. The influence of parameters such as type of carrier and drug-carrier interaction was investigated. Sustained release solid dispersions of flurbiprofen were prepared by solvent method using Eudragit RS 100 and Eudragit RL 100 as carriers. Five proportions were used in both cases. All solid dispersions showed extended drug release as compared to pure flurbiprofen. Eudragit RS 100 solid dispersion showed greater retardation of drug release than Eudragit RL 100 solid dispersions. Thin layer chromatography and infrared spectroscopy indicates no interaction between the drug and the carriers.

AP80 Osmotic controlled delivery of atenolol from asymmetric membrane capsules

S. Bharath* & Shobha Rani R. Hiremath[1]

* M.S.Ramaiah college of Pharmacy, M.S.R.I.T.Post, Bangalore-54.

1. Al- Ameen College of Pharmacy, Hosur Road, Bangalore – 27.

Osmotic controlled drug delivery systems have found to produce more significant use in pharmacotherapy of cardiovascular drugs. Several types of osmotic delivery devices are being developed but most of them lag behind because of its process complication, long duration for manufacture and also the cost factor.

Thus in the present work to overcome the above drawbacks, the concept of "asymmetric membrane capsules" was studied which is new and novel using the cardiovascular β-blocker drug atenolol.

Asymmetric membrane capsules of cellulose acetate with concentrations between 10-25% w/v was prepared using fabricated mini lab model capsule shell manufacturing machine by phase inversion wet process method.

The different formulations were made with additives PVP,Hv-NaCMC as osmopolymers in different ratios. The optimization technique was generated for screening the variables which affect the invitro release kinetics and to select the formulation which can release the drug upto 24hr. using the Plackett-Burmann factorial design of the soft ware Design Expert.

X-ray Diffraction and Differential Scanning Calorimetry analysis was performed with pure samples of drug atenolol, excipients PVP & Hv-NaCMC and drug : excipient (1:1) mixture to study the drug – excipient interaction.

The formulation with capsule shell content

CA-10%w/v, osmopolymers PVP and Hv-NaCMC (0.5 : 0.5) ratio of the drug content showed controlled and complete release of atenolol upto 24hr. The polynomial equation was generated to quantify the effects of the additives on the cumulative percent release of the drug.

X-ray diffractometry indicated no interaction between the drug and excipients and DSC studies confirmed the X-ray diffractometry results.

AP 81 Drug carriers for controlled drug release

Baheti D.G., Tare M.S.*, Page A.B., Bande S.P, Redasani V.K., Rane M.A., Ware V.V.

SCSSS College of Pharmacy, Shirur (Pune)412210

Pellets are of great interest, as a drug delivery system, due to variety of reasons. This particle coating method has gained more importance with the advent of sustained and controlled release dosage forms. In this technique it involves the use of carriers. They act as diluents, which not only improve the distribution on the ingredients present in minute quantities, but also serve to keep the ingredients separated, forestalling any premature ingredient interaction.

The appropriate carrier will not affect the finished product. Since carriers are considered process aids and are frequently omitted from the product label. They provide no nutritional or ingredient functionality in the finished product.

Upto the date Non pareil seeds of sugar and other materials have been used as drug carriers in sustained & controlled release dosage forms. Excepting some materials, these are not so easily available. It was therefore considered of interest to prepare inert cores by using simple pan coating technique and to evaluate them for their suitability as drug carriers.

The primary object of the present study therefore was to develop and standardize the process for production of spherical particles of inert materials from natural source.

For this purpose coarse powder of *Tapoica sago*, Bhagar (varai rice) & Black Mustard were tried as the diluent material for production of spherical particles using Simple pan coating technique.Result of this study showed that Bhagar (varai rice) with solution layering method was found to be suitable in terms of mechanical strength & flowability for the production of inert cores in controlled release dosage forms.

AP 82 Application of optimisation technique in formulation of buccoadhesive dosage form of captopril and its evaluation"

Fatima Sanjeri Dasankop*, N.G. Nanjunda Swamy[1], Arun Kumar[2]

Dept. of Pharmaceutics, K.L.E.S. College of Pharmacy, Hubli 580 031

Captopril an antihypertensive drug which undergoes extensive first pass metabolism on oral ingestion and also gets degraded in the intestine. In the present investigation, optimisation technique was used to fabricate buccal muccoadhesive tablets of captopril to determine the value of variable factors in the formulation to get the desired released kinetics. In this study carbopol-934 (a bioadhesive polymer) and hydroxypropylmethylcellulose (HPMC) 4K, 15K (to control the drug release) were used and the tablets were fabricated by direct compression technique. The formulations trials were designed based on 3 factorial at 2 levels (2^3 factorial design) using Design Expert software. Totally eight runs (formulations) were conducted according to the model.

The formulations were evaluated for drug content, bioadhesive strength (rabbit mucosa) and release rate profiles using dissolution apparatus U.S.P method II (paddle). The release rate constant, diffusion coefficient were calculated using curve fitting method. The polynomial were developed for each response. From the polynomial equations the value of polymers for desired response from the formulation was determined by Design expert software. The optimum formulation was evaluated for the Physical, Chemical and biological parameters. The dissolution data of Captopril was found to fit Krosmeyer and Peppas release kinetics with the regression of 0.9966 and diffusion was fickian in nature. In vivo studies were carried out using rabbit as the animal model. The Pharmacokinetic data revealed C_{Max} as 70.54 ng/ml and T_{Max} as 4 hrs. While for a conventional tablet the T_{Max} is 2 hrs. From the present investigation it can be concluded that captopril muccoadhesive buccal tablets appears to be controlled release dosage form to increase its bioavailability and effective drug utilization.

AP 83 Molecular encapsulation of fenofibrate in β-cyclodextrin

Patel A.R.* and Vavia P. R.

Pharmaceutical Division, University Institute of Chemical Technology, Nathalal Parikh Marg, Matunga, Mumbai 400019

Cyclodextrins; by virtue of formation of a water soluble inclusion complex; have been known to

increase the solubility and dissolution of poorly water soluble drugs, thus enhancing the rate of absorption and bioavailability of hydrophobic drug molecules. Inclusion complexation of fenofibrate, a Cholesterol lowering agent, belonging to the class of fibric acid derivatives, was attempted with β-Cyclodextrin, using the slurry and grinding techniques. Physical mixtures of Fenofibrate and β-Cyclodextrin were also prepared by mixing the powders in geometric proportions. The phase solubility studies performed, confirmed the solubility enhancement capabilities of β-Cyclodextrin, suggesting existence of a 1:1 complexation between Fenofibrate and β-Cyclodextrin in solution. Characterization of complexes ensured the formation of new solid phases (i.e. Complex formation).

The in-vitro dissolution of Fenofibrate, physical mixtures and complexes was studied in distilled water. The complexes prepared by slurry method and grinding method were compared by means of the in vitro dissolution studies. Complexes prepared by both the methods were found to be equivalent with respect to drug solubility enhancement. The drug-β-Cyclodextrin complexes exhibited faster dissolution rates as compared to the rate profile of physical mixtures and drug alone. This may be due to the increased solubility and wettability along with the decrease in crystallinity caused by complex formation. The tablets containing Fenofibrate-β-Cyclodextrin complex showed better release rate as compared to conventional marketed preparations.

AP84 Studies on topical formulations of valdecoxib

A. A. Modi[1], P. T. Tayade[2]*.

1. The Bombay College of Pharmacy, Santacruz (E), Mumbai 400098.
2. University Institute of Chemical Technology, Mumbai 400 019

Valdecoxib, a novel COX-2 inhibitor has been reported to be used in various osteopathic and rheumatoid conditions as oral therapy. Since it is poorly water-soluble, various attempts have been made to increase its solubility. However, there has been no data regarding its topical application. The present study deals with formulation of valdecoxib as topically applied gel formulations with original drug crystals and using its solubilized forms. Valdecoxib-PVP solid dispersion and Valdecoxib-Sulfobutyl ether 7 β-Cyclodextrin complexes was prepared for enhancement of its aqueous solubility. Carbopol 934 P, Hydroxy ethyl cellulose gels were prepared. All formulations were examined for appearance, drug content, drug content uniformity, pH, clarity, viscosity, spreadability, extrudability, in vitro permeation studies using rat skin, efficacy studies using rat and pharmacodynamic studies using human volunteers. Formulations containing drug in its solubilized form was found to be having better permeation and release characteristics. It can be concluded that valdecoxib can be successfully formulated as topical formulation.

AP85 Studies on intragastric buoyant nimesulide hollow microsphers as controlled drug delivery

A. Seshasayana*, K. Hima Sankar, B. Satya Sirisha, L. Srinivas and K. V. Ramana Murthy

Dept. of Pharmaceutical Sciences, Andhra University, Visakhatnam 530 003

Hollow microspheres are better suited for controlled delivery of the drugs with site -specific absorption at gastric region or upper parts of small intestine due to their floating on gastric fluid. As the hollow microspheres are non effervescent and multiple unit delivery systems, they float uniformly on the gastric fluid of the stomach. This uniform distribution could result in more reproducible drug absorption and reduced risk of local irritation than the use of single-unit dosage forms. In the present investigation hollow microspheres of nimesulide using Eudragit S100 by Emulsion solvent diffusion technique were prepared and evaluated for their applicability as gastric retention systems.

Hollow micropheres were prepared in different coat core ratios. The prepared hollow micropheres were discrete, spherical and free flowing. Low values of standard deviation in respect of drug content indicated uniform drug distribution in all the prepared batches. The encapsulation efficiency of the hollow microspheres was found to be in the range of 82-95% in all the ratios of microspheres indicated the suitability of the method with minimum loss of drug during the process. The encapsulation efficiency reduced as the concentration of polymer increased. The hollow microspheres were able to float for more than 24 hrs. on the dissolution medium with no floating lag time. This confirms their applicability as floating drug delivery systems. The IR and X-Ray diffraction spectroscopy studies revealed no interaction between the drug and the polymer used in the preparation of hollow microspheres. The SEM microphotographs showed the smooth texture of surface and the cross sectional view confirmed the hollow nature of the micro spheres. The drug release from the hollow microspheres depended on the polymer ratio 1:3 hollow microspheres showed consistent and controlled release over a period of 12 hrs. compared to commercial sustained release tablet (<5 hrs.). The release of nimesulide from hollow microspheres followed zero order kinetics with diffusion mechanism.

AP 86 Floating microspheres of piroxicam for use as sustained release dosage form

Rajendrakumar Kale[1], Pralhad Tayade[2]*

1. The Bombay College of Pharmacy, Santacruz (E), Mumbai 400098.
2. University Institute of Chemical Technology, Mumbai 400 019

A floating type dosage form in the form of hollow microsphere, loaded with piroxicam in their outer polymer shells, was prepared by emulsion-solvent diffusion method using an enteric polymer, Eudragit S100. Microspheres having a mean diameter in the range of 250-1000 µm and entrapment efficiency of 60-80% were obtained. Scanning electron micrographs showed that incorporation of drug altered the surface morphology of piroxicam microspheres to a significant extent. Differential scanning calorimetry and X-ray diffraction studies showed that drug incorporated in the outer shell of the polymer was found to be partially or completely amorphous. The micromeritic properties of microspheres were much improved compared with original drug crystals. The microspheres remained buoyant continuously over the surface of acidic media containing surfactant for a period of 8-12 hours in vitro. The in vitro drug release behavior of the floating microspheres was characterized as an enteric property. Polymer being soluble above pH 7.0, the drug release rates from microspheres changed dramatically above and below pH 7.0. At intestinal pH the drug release was faster and continuous as compared to the amount released at gastric pH.

AP 87 Design and evaluation of timolol maleate nanoparticles for anti-glaucoma activity

P. Seenivasan*, C. Vijaya, S. Jayaprakash, M. Ramaswamy, L.S. Sathyapriya and M. Nagarajan

K.M. College of Pharmacy, Uthangudi, Madurai Tamilnadu 625 107

Timolol maleate is available as eye drops, treatment has continued for 1 or 2 months and this dosage form has several draw backs such as loss of drug from tear flow, lesser absorption, frequent administration and patient non-compliance. Hence, nanoparticles of Timolol maleate was formulated to over come the above said drawbacks. Nanoparticles of Bovine serum albumin embedded with Timolol Maleate are prepared by denaturation followed by chemical cross –linking methods in the proportion of drug polymer ratio 1:0.5, 1:1 and 1:2. Prepared nanoparticles were evaluated by physico chemical evaluation and infrared spectroscopy study. The prepared nanoparticles have distinct advantages over conventional eye drops as evidenced by invitro drug release study carried out by using dialysis membrane. From the invitro study it shows that the conventional eye drops release 100% drug at the end of 2 hours. Whereas in nanoparticles prepared by chemical cross linking method release the drug only 74% at the end of 12 hours. The invivo studies are carried out by using rabbits. The glaucoma induced to the rabbits by sub-conjunctival injection of Betamethazone. The intra ocular pressure (IOP) are measured by using Schiotz tonometer. Invitro and invivo studies are well correlated. The mechanism of drug release from the nanoparticle is matrix diffusion in agreement with Highuchi model. The sterilization and sterility testing of nano particles are carried out. From this study the following parameters like particle size, color, clarity, pH after and before sterilization are same, which indicates that the sterilization method did not affect the physicochemical properties of the drug as well as the formulation. Hence the prepared nanoparticles have distinct advantages over conventional eye drops as evidenced by invitro and invivo study. The objectives of controlled release, increased therapeutic efficacy and decreased frequency of administration achieved by the prepared nanoparticles.

AP 88 Formulation and evaluation of niosomes containing diclofenac potassium

***B.S. Venkateswarlu, A. Pasupathi, B. Jayakar, R. Margret Chandra[2] & T.V. Narayana**

Vinayaka Mission's College of Pharmacy, Salem - 8

Diclofenac potassium is an analgesic antipyretic and antiulcer, antiinflammatory activities. It is an inhibitor of cyclooxygenase and its potency is substantially greater than that of indomethasine napraxene and several othe agents.

It is idealy suited for patients for sodium free diet, hypertensive patients to treat painful inflammatory condititon to patients on diuretic therapy.

In this present work an attempt was made to study the effect of niosomes on the release behaviour of diclofenac potassium. The niosomes were formulated by lipid film hydration techniques and it was bysize distribution, stability studies an invitro release studies. Stability studies were carried out at different temp, like 4°c, room temp, and 45°c it has shown that the niosomes were more suitable in 4°c when compared with room temp and 45°c.

Invitro release studies by dialysis technique,In this pure drug was released 26.72% of Drug in 1 hr and the maximum 96.18 was released within 5 hours. At the same time the liposomal formulation release the drug continously for 24 hours period it released only 11.72% of diclofenac potassium in 1 hr and vithin 24 hours study period it releases only 73.18% of diclofenac potassium. From the above studies we concluded that the neosomal formulation showed better sustained action.

AP 89 Solid lipid nanoparticles of methotrexate for the treatment of psoriasis

Mayur Kalatiya*, Ambikanandan Misra

Pharmacy Department, Faculty of Tech. and Engg., M. S. University of Baroda. Vadodara.

The purpose of this study was to incorporate drug into solid Lipid Nanoparticles (SLNs) and to improve percutaneous absorption of the drug for the treatment of Psoriasis. Methotrexate (MTx), a folic acid antagonist was selected for incorporation into SLNs using microemulsion solidification technique. Formulation variables, such as Drug : Lipid molar ratio, type of Lipid, concentration of emulsifier. and type of coemulsifier were optimized employing Taguchi Orthogonal Experimental Design using four variables at three levels for SLN's mean particle diameter and drug encapsulation efficiency. Methotrexate loaded SLNs and plain drug were incorporated into O/W cream base and *in vitro* skin permeation through human cadaver skin were compared using Franz diffusion cell. The data of SLNs mean particle diameter and drug encapsulation efficiency among different formulations were compared using multiple regression analysis and difference larger than $p < 00.5$ were considered significant. The results showed that selected formulation variable had a significant influence on the mean particle diameter and encapsulation efficiency of SLNs. The *in vitro* diffusion studies conducted using human cadaver skin resulted into higher drug deposition into the skin after incorporation into SLNs. Hence, developed formulation under investigation is expected to treat the disease psoriasis more effectively after incorporation of the drug into SLNs.

AP 90 Transdermal films of ketoprofen and study of effect of thickness

S.S. Shyale, S.M. Shantakumar, S.Chemate, Sabitha, A.Sreekanth*

Dept. of Pharmaceutics, V.L. College of Pharmacy, Raichur 584103

Several transdermal films of ketoprofen in PVA matrix as drug reservoir were casted with EC as rate controlling membrane. The aim of the current investigation was to study the effect of increasing thickness of rate controlling membrane over the drug release kinetics using different mathematical models. Several EC films of varying thicknesses were fabricated from 30 ìm to 125 ìm and casted over PVA drug matrix film. The physical characteristics of the films prepared were evaluated using standard techniques and methods. In vitro release studies were conducted in Keshary-Chien diffusion cells and in vivo activity for the drug was done using albino mice and rats.

It was observed that, zero order drug release seems to be apparent when Cumulative percentage drug release was plotted against time, since the curve obtained is a straight line. But, with korsemeyer data the linear curves will have different slope values and the drug release data approaches zero order mechanism (n= 1) only at a particular thickness. In our investigation, perfect zero order release was seen at 125mm thickness of EC film. Significant analgesic and anti-inflammatory activity was observed at $p < (0.001 - 0.01)$.

AP 91 In-vitro release studies of gelatin buccal discs containing ciprofloxacin –HCl

S.Ṡ. Shyale, M.B.Raju, Mrs. S. Sreelatha Adiga, and Aashima H.,*

Dept of Pharmaceutics, V.L.College of Pharmacy, Raichur 584 103, Karnataka

The current work was aimed at preparing discs of Gelatin for mucoadhesion using a model drug Ciprofloxacin HCl. A simple equipment was fabricated to study the relative bioadhesion. The discs were studied for various physico-chemical properties and also in vitro release pattern. The release mechanism was ascertained using Korsemeyer's equation for discs..

Various physical characteristics of the disc, thickness, diameter, surface pH, and weight of the discs remained uniform and consistent indicated by their low percentage coefficient of variation. The swelling behavior was observed to increase with time. The bioadhesion equipment was validated and the results obtained were satisfactory. Bioadhesion strength was observed to increase with increasing amounts of Gelatin and increasing proportion of Carbopol-934p as copolymer. Also, Dibutyl phthalate in 15%w/w of gelatin increases the bioadhesive strength than Glycerol 15%w/w.

In vitro release studies were carried out in USP XXI – dissolution apparatus-method II, using 100ml of phosphate buffer of pH 6.6, as media. The results showed that, all the formulations follow zero or near zero order release after initial swelling. Also, by substituting a part of gelatin with Carbopol-934p, at 7.5% weight of gelatin perfect zero order release (n=1) was observed. And including 15% w/w DBP to gelatin discs decreases the release rate of ciprofloxacin.

AP 92 Skin permeation studies of few ACE inhibitor antihypertensive agents

S.S. Shyale, S.M.Shantakumar, C.Anand and M. Balakrishnaiah*

Dept of Pharmaceutics, V.L. College of Pharmacy, Raichur 584 103, Karnataka

This investigation was taken up to study the feasibility of a water-soluble ACE-inhibitor antihypertensive drug Captopril, and also two poorly water-soluble ACE-inhibitor prodrugs Enalapril maleate (Enalapril-M) and Ramipril for transdermal delivery. All the drugs and prodrugs chosen for the study have short biological half life.

Various physical parameters like solubility in various solvents and their mixtures, melting point partition coefficient etc., were determined using standard techniques. Permeation studies across depilated swiss albino rats skin were conducted in Keshary-chien diffusion cells.

Solubility of the drugs in the various solvents viz., distilled water, ethanol, and ethanol: water 50:50, were determined. In the solvents selected for the study Captopril is highly soluble followed by Enalapril maleate and Ramipril. pH of the drug solutions in distilled water at 20 °C are reported. Octanol: water partition coefficient at 20°C was determined and was found to be 00.16, 00.46 and 00.56 for Captopril, Enalapril – M and Ramipril respectively. Gradual increase in partition coefficient is observed. Log kp values were calculated using Pott's and guy equation and were found to be - 4.59, - 5.94 and – 5.42 for captopril, enalapril - M and ramipril, respectively. From the solubility in distilled water and partition coefficient studies it was seen that as the solubility of the above drugs in distilled water increases, partition coefficient gradually decreases. In this work it is observed that, as partition coefficient of the drugs in the series increases the steady state flux decreases.

In this investigation it is observed that ACE inhibitors including their prodrugs can be utilized as potential candidates for transdermal delivery.

AP 93 Betamethasone liposomes for topical use: development, characterization and in-vitro evaluation

Neetika Vij[1], Rajiv Khurana[2] and O. P. Katare[2*]

1 Ind-Swift Laboratories, Dera-Bassi, Punjab

2 University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh - 160 014

Betamethasone, an anti-inflammatory glucocorticoid is the treatment of choice for nearly all the itchy and inflammatory dermatoses and many hyperproliferative skin disorders such as eczema and psoriasis. The drug is available for topical application in various conventional dosage forms, however the poor skin penetration of the skin, local adverse effects on skin and systemic toxicities associated with percutaneous absorption of the drug demands improvement in the formulation design. In this study, betamethasone has been encapsulated into multilamellar liposomes composed of soya lecithin and cholestrol with an aim to modulate the skin transport and localize the drug molecules in the deeper layers of the skin strata. Optimization of various preparatory parameters yielded a homogenous population of vesicles, with drug loading as high as 93.01% (drug-lipid ratio: 1:15). Transmission electron microscopy and Malvern Mastersizer assisted morphological and micromeritic analysis revealed the spherical nature and uniform size distribution of the betamethasone-loaded liposomes with an average vesicle diameter (d_{50}) of 8 microns. Upon stability assessment the liposomes were shown to retain the drug up to 94% in the refrigerated storage in a 4-week period. The in-vitro drug release studies across dialysis membrane and skin permeation studies carried out on mouse skin, reveal the controlled release character of different betamethasone loaded liposomal systems (i.e., liposomal suspension, liposomal cream and liposomal gel) when compared to aqueous solution, carbopol gel and conventional o/w cream of betamethasone. The skin uptake studies showed higher drug accumulation with liposomal suspension, liposomal gel and liposomal cream, thereby indicating the ability of multilamellar vesicles to form micro-reservoirs or induce an atmosphere suitable enough to provide a depot effect. The studies lead to conclusion that betamethasone encased within the phospholipid bilayers has appreciable potential in making the drug molecules available at the skin-target site to help extend and enhance the desired effect.

AP 94 Lecithinised microemulsion of flurbiprofen for topical delivery: preparation, characterization and evaluation

Manmeet Kaur[1], Rajiv Khurana[2*] and O. P. Katare[2]

1. Dr. Reddy's Research Laboratories, Hyderabad, INDIA

2. University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh - 160 014

The aim of the current study was to incorporate flurbiprofen, a potent anti-inflammatory agent, in the phospholipids-based microemulsion and evaluate the topical performance in-vitro. Various constituents of the lecithin microemulsions viz. suitable oil for internal oily core containing phospholipid (saturated soyabean lecithin) and cosurfactants such as tween 20, tween 80, span 20 and propylene glycol were tried in different concentrations to obtain the microemulsion with desired characteristics. The optimized formulation (Formulation FA) contained isopropyl myristate (10%), lecithin (0.5%), Tween 80 (2.5%) in the microemulsion containing 0.5% w/w of flurbiprofen. The size of the microdroplets of internal oily core, determined by Malvern Particle Size Analyzer was found to be in the range of 0.3–4.19 mm. TEM photographs obtained by negative staining of the sample of formulation,

revealed the spherical shape of the lipid globules. For onsite application, the viscosity of the microemulsion was enhanced employing 1% w/w carbopol gel (Formulation FB) while maintaining the equal drug concentrations in both the formulations. Both the formulations FA & FB were found to be stable at 4ºC, 25ºC and 40ºC for a period of 7 weeks in terms of phase separation, viscosity change, pH change and drug precipitation.. The rheological studies carried out on formulation FB employing Brookfield's viscometer indicated near-Newtonian nature of the microemulsion. Spreadibilty of the formulation FB was determined using texture analyzer. Significantly enhanced release of flurbiprofen from microemulsion-based formulations (release flux: 79.17 mg/cm²/h and 70.20 mg/cm²/h for FA & FB respectively) along with the higher transdermal flux 31.67 mg/cm²/h and 25.98 mg/cm²/h for FA & FB respectively have been noted compared to conventional flurbiprofen gel (drug release flux: 22.35 mg/cm²/h, transdermal flux: 18.5 mg/cm²/h) and conventional cream base containing flurbiprofen (drug release flux: 11.78mg/cm²/h, transdermal flux: 19.6mg/cm²/h). Significantly higher ($p<0.05$) reduction in the paw oedema volume was observed with lecithin microemulsion based formulation of flurbiprofen when compared with drug dispersed in o/w cream base. Thus a stable delivery system, exhibiting enhanced therapeutic performance could be developed for topical delivery of flurbiprofen.

AP 95 Preparation and in-vitro evaluation of mucoadhesive chitosan microspheres of amlodipine besylate for nasal administration

S.B. Patil* , R.S.R. Murthy

A.R.A.College of Pharamacy, Nagaon, Dhule(MS)

Amlodipine besylate, calcium channel blocker, is a drug of choice in the treatment of hypertension and angina pectoris. Amoldipine besylate undergoes first pass metabolism by oral route and thus exhibit only 60 – 65 % oral biavailability. The present investigation was aimed at avoidance of first pass metabolism of amlodipine besylate by prepaing chitosan microspheres for nasal administration.

A series of batches of chitosan microspheres were prepared by simple emulsification crosslinking method to optimize parameters like external phase (mixture of heavy and light liquid paraffin in the ratio of 1: 1), stirring rate (1200 rpm), dioctyl sodium sulffosuccinate (DOSS) concentration (0.2 % w/v), chitosan : drug ratio (2 : 1) , volume of crosslinking agent (glutaraldehyde) (1 ml) and time of crosslinking (3 hours). The microspheres were subjected to evaluation for physical characteristics such as particle size, scanning electron microscopy (SEM), drug entrapment efficiency, in vitro mucoadhesion, in vitro drug release characteristics.

The microspheres had a median particle size of 36.47 ± 3.39 mm suitable for nasal administration. Electron microscopy revealed that microspheres were spherical with slight smooth surface morphology. The percentage drug entrapment ranged from 40.8 % to 72.57 %. In vitro mucoadhesion ranged from 61.21% to 70.43 %. Application of in vitro drug release data to various kinetic equations indicated matrix diffusion controlled drug delivery from chitosan microspheres.

In conclusion these results indicates that the chitosan micropheres of amlodipine besylate are suitable for nasal administration to avoid first pass metabolism of amlodipine besylate to improve the bioavailability.

AP 96 Design and evaluation of sodium alginate/ethyl cellulose mucoadhesive bilayered films for buccal drug delivery

B.K.Satish babu*, B.P. Srinivasan

College of Pharmacy, Pushp Vihar Sector 3, New Delhi - 17

This work describes the preparation of new buccal bilayered films comprising a drug containing mucoadhesive layer and a drug free backing layer were produced by a casting/solvent evaporation technique. The mucoadhesive layer was composed of a mixture drug i.e. Atenolol and sodium alginate with or without carbopol 934p (0%, 10% and 50%). The backing membrane was made up of Ethyl cellulose. Double distilled water was used as solvent for the preparation of mucoadhesive layer. 10%w/w glycerin was added as plasticizer. The backing membrane made upon by Ethyl cellulose (5%) in 70:30 Acetone and Isopropyl alcohol Dibutylphthalate as plasticizer. The double-layered films were expected to provide drug delivery in a unidirectional fashion to the mucosa and avoid loss of drug due to washout with saliva. The prepared films were subjected to physical parameters like thickness, weight variation, water vapor transmission tests. The drug release studies were carried out in phosphate buffer saline pH 7.4 and in vitro drug permeation studies carried out using modified Franz diffusion cell using fresh porcine membrane and analyzed spectrophotometricaly. The prepared films were characterized by scanning electron microscopy and FTIR.

AP 97 Preparation and evaluation of diltiazem hydrochloride loaded albumin microspheres

Jani Girish K.[1], Chauhan Manish[1], Prajapati Vipul*[2]

1. Department of Pharmaceutics, L. M. College of Pharmacy, Ahmedabad.

2. Department of Pharmaceutics, Shri Sarvajanik, Pharmacy College, Mehsana.

Diltiazem hydrochloride (DH), a coronary vasodilator known as calcium channel blocker, is widely used in the treatment of angina pectoris, arrhythmias and hypertension. It has a short elimination half life ($t_{1/2}$ = 3 – 5 hours) and needs frequent dosing. To achieve several advantages over its sustained release tablets – the development of homogeneous monolithic drug delivery system (microspheres) is required.

In the present investigation, DH loaded albumin microspheres were prepared by w/o emulsion thermal cross-linking method and supplied in capsule. Aqueous albumin solution, light liquid paraffin (LLP) and span 60 were selected as a dispersed phase (DP), dispersion medium (DM) and surfactant respectively. During preparation different process variables like concentration and volume of DP, types and volume of DM, types and concentration of surfactant, thermal cross-linking temperature, time and stirring speed were evaluated and optimized. For DH loaded microsphere independent variables - Drug: Polymer (D: P) ratio, volume of DP and surfactant concentration and dependent variables - % drug loading were evaluated and optimized to 1: 1 (750mg: 750mg), 10ml 7.5 %w/v of aqueous albumin, 0.4 % surfactant by a 3^2 factorial design.

Optimized best batch of microsphere showed highest (79.20 %) drug loading with small spherical particle (GMD = 47.5 ± 0.5microns) by optical microscopy with moderate aggregation and used for further evaluation like in-vitro drug release and its stability. To prevent burst effect optimized best batch was coated with ethyl cellulose (optimum 7.5 %). In-vitro dissolution study from capsule revealed that microspheres sustained the release of drug up to 12 hrs as that from the market preparation and alone microspheres. Accelerated stability study (at 40° ± 2° C, 75 ± 5 % RH) for one month showed no significant change on release profile, physical characteristics and drug content.

AP$_{98}$ Development and evaluation of buccoadhesive systems of pentazocine

J.K. Pandit, M. Thilek Kumar, D. Sampath Kumar* and K. Balamurugan

Department of Pharmaceutics, Institute of Technology Banaras Hindu University, Varanasi - 221 005.

Pentazocine (PZ) oral mucoadhesive patches were prepared by casting using carboxy methyl cellulose (CMC) with glycerol or propylene glycol and CMC- hydroxy ethyl cellulose (HEC) with glycerol. In vitro mucoadhesivity of the prepared patches were determined using a modified mucoadhesive bond strength apparatus developed by us using rabbit small intestine mucosa (SIM). drug release kinetics were evaluated using an in house developed apparatus using composite patches, prepared by covering the PZ patches with 3M backing material, to ensure unidirectional drug release. Biocompatability/ buccoadhesion time and in vivo permeation of the patches (placebo and PZ) were determined using a double blind cross over study in healthy human volunteers. Drug release from CMC glycerol patches and pure HEC patches showed zero order drug release with diffusional exponent (n) ranging between 0.79 to 1.046, while that from CMC-HEC and CMC-propylene glycol patches showed an apparent zero order release kinetics. The prepared patches were well tolerated by the human volunteers as they did not produce any side effects at the contact surface and the in vitro mucoadhesivity of CMC-propylene glycol patches were significantly lower than CMC- glycerol based patches. The in vivo permeation of the selected PZ patches delivered the drug well above the minimum buccal permeation rate, so as to attain effective blood concentration.

AP$_{99}$ *In-vitro* and *in-vivo* evaluation of gellan-based scleral implants of indomethacin

J.K. Pandit, J. Balasubramaniam* and M. Thilek Kumar

Department of Pharmaceutics, Institute of Technology Banaras Hindu University, Varanasi - 221 005.

Film type scleral implants of indomethacin with gellan gum were prepared by solvent casting and evaluated for uniformities of thickness, weight, drug content and surface pH. The effect of plasticizers like glycerol, propylene glycol (PG), polyethylene glycol (PEG) 200 and 400 on the void volume of free gellan films (placebo) was calculated from the water content of the films. The drug release from the prepared implants was determined using a static dissolution set up developed and optimized in our laboratory. Based on the results of the void volume and initial drug release studies, glycerol and PG were selected as the plasticizers for the gellan-based implants. The morphology of the drug free films (containing 10 and 40% of PG) and the drug-loaded films (before and after dissolution and cross-linked) were studied using scanning electron microscopy (SEM). Further, the effect of plasticizer concentration, gellan concentration, effect of cross-linking technique and duration of cross-linking using calcium chloride on in vitro drug release characteristics were evaluated. Selected batches of the implants were subjected to pharmacodynamic studies, after scleral placement, in uveitis induced (intravitreal injection of Bovine Serum Albumin-BSA- 50mg / ml) rabbit eyes. The release of indomethacin from the prepared implants followed matrix diffusion kinetics with diffusion co-efficient (n) values ranging between 0.358 to 0.708 and seemed to depend on both gellan

and plasticizer concentration. Surface cross-linking with 10% calcium chloride for 8 hours retarded drug release (1.42 times less than non cross-linked implant) and was found to be optimum. The pharmacodynamic studies showed a marked improvement in the various clinical parameters (congestion, keratitis, flare, clot, aqueous cells and synechias), in the implanted eye when compared to the control eye in the rabbits. The scleral implants survived up to 3 weeks in vivo.

AP100 Ion and pH induced in-situ gelling systems of indomethacin for sustained ophthalmic delivery

M. Thilek Kumar, K. Balamurugan, B. Preethi and J.K. Pandit*

Department of Pharmaceutics, Institute of Technology Banaras Hindu University, Varanasi - 221 005.

The low bioavailability and ocular residence time exhibited by the topical conventional liquid ophthalmic formulations because of spillage by overflow, dilution of drug by tear turn over, nasolacrimal drainage and systemic absorption may be overcome by the use of in situ gel forming systems that are instilled as liquid drops into the cul-de-sac of the eye, where they transform into a gel or semisolid phase. The present work describes the formulation and evaluation of an ophthalmic delivery system of an anti-inflammatory drug, indomethacin for the treatment of uveitis based on the concept of ion and pH induced in situ gelation.

Sodium alginate, an ophthalmic vehicle, which gels in the presence of mono- or divalent cations, present in the lacrimal fluid was used in combination with Carbopol 974P which transform into stiff gels upon increase in pH of eye as the gelling agents, and hydroxy propyl methyl cellulose - $K_{15}M$ (HPMC), as a viscosity enhancing agent. A series of combinations of Sodium Alginate- HPMC and Sodium Alginate-Carbopol 974P were prepared and their in vitro evaluation was conducted. In vitro evaluation in experimentally uveitis-induced rabbit eye showed that Carbopol 974P produced an additive pharmacodynamic activity in the resolving the uveitis descriptors in the rabbit eye model.

AP101 Synthesis and evaluation of modified / cross-linked gum acacia as sustained release drug carrier

Tilak R. Bhardwaj, Meenakshi Kanwar, Roshan Lal Sandal and Manoj Kumar

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh- 160 014, India.

The present study describes the use of gum acacia after various modifications, in the sustained release of diclofenac sodium. Oral controlled release systems are widely used despite advancements made in other drug delivery systems. Matrix tablets offer advantages such as ease in formulation development and manufacturing. Polymeric materials already in use are costly and availability of these materials in India is limited. Hence, the objective of this work is to make inexpensive, biocompatible non-toxic material from natural gums by chemical modifications, which would be further used as a carrier for sustained release dosage forms. Therefore, these may be import substitutes for polymeric materials used in the controlled drug delivery systems.

Initially gum acacia was chemically modified and its various derivatives were prepared: methyl gum acacia, sodium carboxymethyl gum acacia, and hydroxypropyl gum acacia. All these modifications of gum acacia were used for developing matrix tablets of diclofenac sodium in different drug to polymer ratios. The formulations were evaluated by their drug release profiles *in vitro* in phosphate buffer (pH 6.8) as the dissolution medium. All these formulations were compared with two marketed brands and matrix tablets prepared using hydroxypropyl methylcellulose as standard polymer.

As it was evident from the physicochemical properties and dissolution studies that these modified gums have undergone degradation during modification. Therefore, it was considered of interest to do crosslinking. Gum acacia was crosslinked with poly (vinyl alcohol) poly (ethylene & glycol) using glutaraldehyde as the crosslinking agent in addition to self crosslinking.

Gum acacia and its various modified products were characterized by determination of ash values (total ash content, water-soluble ash, acid-insoluble ash and sulphated ash), loss on drying percent hydroxyl value, solubility, differential scanning calorimetric studies, swelling index, IR spectroscopy, viscosity determination / rheology, and pH determination.

Gum acacia self cross-linked and crosslinked with poly (vinyl alcohol) and poly (ethylene glycol) prolonged the release of diclofenac sodium to 24 h, 18-24 h and 12-18 h, respectively. It was observed that as the content of the polymer was increased there was decrease in drug release rate (DRR) and increase in $t_{50\%}$ values. The drug release profiles of gum acacia self cross-linked and cross-linked with poly (vinyl alcohol) and with poly (ethylene glycol) showed non-fickian diffusion, fickian diffusion and zero -order release characteristics respectively. These modifications with gum acacia showed promising results as sustained release drug carriers.

AP 102 Studies on vegetable oil based extended release ophthalmic formulations of flurbiprofen

Sajeev C.*, Atul P. V., Archna R., Saha R. N.

Pharmacy Group, Birla Institute of Technology and Science, Pilani 333 031 (Rajasthan)

In the present study an attempt was made to develop extended release ophthalmic formulations of flurbiprofen using highly pure (parenteral grade) vegetable oils like, cottonseed, olive, arachis, castor, sesame and linseed. The formulations were evaluated for appearance, clarity, odour, pH, drug content, flow property, spreadability and mucoadhesiveness. Effect of oil type was studied on in-vitro dissolution character and in-vitro transcorneal permeability (on goat cornea) from designed formulations. Selected formulations were evaluated for ocular safety using Draize's test protocol and for ocular bioavailability. Also investigated was batch reproducibility and stability on storage and the effect of storage conditions on the shelf life of selected formulations.

All formulations possessed the characteristic odour and appearance peculiar to each oil type and were also found to possess good drug content uniformity, flow property and spreadability. All formulations were buffered at pH 7.6-7.8 and possessed low mucoadhesiveness. The dissolution data from different vegetable oil based formulations exhibited mostly similar release pattern with release extended up to 300 mins in case of formulations prepared using cotton seed oil, olive oil, arachis oil, castor oil and linseed oil whereas in case of sesame oil formulation the release was extended only up to 240 mins. The reason for controlled release of flurbiprofen from oily vehicle could be higher solubility of the drug in the selected oils thereby decreasing the partitioning of the drug into the dissolution media (phosphate buffer, pH 7.4). The drug release from vegetable oil based formulations was found to follow first order drug release kinetics. Low variation in the determined spreadability, mucoadhesiveness, drug content, pH, pourability and release rate constant data for three different batches of each formulation indicated absence of significant batch-to-batch variation. An analysis of the predicted and observed shelf life did not show any difference at $p < 0.01$ in case of oil-based formulations. Studies with selected formulations showed that the transcorneal permeability results of the drug correlated well with the solubility data of flurbiprofen in the respective oil. Ocular safety studies revealed that developed oil based formulations were non- irritating to practically non-irritating to the rabbit eye. In comparison to aqueous drop, selected oil based formulations showed higher t_{max}, lower C_{max} and larger AUC with respect to aqueous humor drug concentration.

It can be concluded that parenteral grade vegetable oil based formulations are plausible alternative for extended release ocular delivery of flurbiprofen or other NSAID's used in ocular pathologies.

AP 103 Design and evaluation buccal delivery systems for better delivery of drugs

K. Sasank Chaitanaya, Shrikant Y. Charde* and Saha R. N.

Birla Institute of Technology and Science, Pilani 333 031 (Raj)

Amongst the various routes of drug delivery, oral route is perhaps the most preferred to the patient and to some clinicians alike. However, oral administration of drugs has disadvantages such as degradation within the gastro-intestinal tract (GIT), hepatic first pass metabolism and gastric irritation. These prohibit oral administration of certain classes of drugs especially drugs with above mentioned problems. Buccal route of administration, that bypasses GIT, is therefore highly preferred for such drug as this leads to substantial dose reduction and hence less dose dependent side effects. The objective of this study was to develop a simple buccoadhesive controlled release delivery systems and to study drug release kinetics from the prepared delivery systems using Propranolol hydrochloride (PL), which is a non selective beta blocker and had only 15-23% oral bioavailability due to high first pass metabolism, as a model candidate drug.

Various polymers like ethyl cellulose; hydroxy propyl methylcellulose, polyethylene glycol and polycarbophil were used to control the release of drug from the prepared delivered systems and to achieve optimum bioadhesion. The prepared delivery systems were found to possess good physical attributes like plasticity and folding endurance. Patches showed good mucoadhesive characters. Diffusion studies were carried out for all the prepared delivery systems. The rate of release was found to be inversely proportional to the polymer concentration in patches and extended till 24 hours in some of the cases. No significant variation was observed in the release profile of different batches indicating that manufacturing process employed was reliable and reproducible. The data was fitted into Peppas mathematical model ($Mt/m\infty = kt^n$) and the release characters of different formulations were found to be first order or a combination of zero and first order. Increase in viscosity of HPMC extended the release marginally. HPMC 100000 cps was extending the drug release much beyond 24 hours. It can be concluded that using common polymers like EC, HPMC, PC and PEG mucoadhesive buccal patches can be prepared for 24 hours drug.

AP 104 Preparation and characterization of slow release testosterone nanocapsules

Benoy Brata Bhowmik*, Arup Mukherjee

Division of Pharmaceutical Technology, Department of Chemical Technology, Calcutta University, 92,A.P.C. Road, Kolkata- 700009

Nanocapsules (NC) are submicroscopic colloidal drug carrier systems of oily or aqueous drug core, coated with a thin polymer membrane. NC's provide several biodistribution advantages for their small size and for the associated polymer surface properties. The model drug used was testosterone. Testosterone is a highly lipophillic male steroidal hormone, used for androgenic activity, suppression of breast cancer and prostate cancer, in osteoporosis for calcium retention and in gerontology. It has very short plasma half-life of about 10-20 min., it undergoes extensive first pass metabolism in liver and injectable testosterone pro-drug esters are the only choice for administration. A sustained release testosterone delivery system is therefore a long-standing market demand.

This work is an attempt to nanocapsulate free testosterone in alginate, a biodegradable, biocompatible polymer of natural origin, following a nano-emulsion, in situ polymer cross linking approach. Thus ideally, the drug dissolved in hexane was emulsified in aqueous alginate solution followed by cross-linking in calcium chloride solution. Nanocapsules formed were isolated by ultracentrifugation and the drug content was analyzed in HPLC. The drug release profile was monitored in HPLC and 48hrs release profile was recorded that follows a zero order diffusion model. Particle size was monitored in Photon Correlation Spectroscopy and in Transmission Electron Miocroscopy the average particles diameter was found to be 17.12 ± 1.11 nm. Several experiments were run to optimize solvent requirements, surfactant requirements cross linker requirements etc. The drug loading in harvested nanocapsules was 30.2+5.3% and they can be suitably preserved at 4°C for months.

AP 105 Improvement of dissolution profile of poorly water soluble drug (cefuroxime axetil) by using spraydrying Technique

Abhay V. Goti*, Manish Umrethia, Hitesh Dodiya Amit Raval, R. S. R. Murthy

New Drug Delivery Sxystem Laboratory, Pharmacy Department, Donor's Plaza, The M. S. Uni. of Baroda, Fatehgunj, Vadodara-2

Cefuroxime axetil (CXA) is a second generation cephalosporin antibiotic used in various infection like urinary and respiratory tract infection. One of major problem with CXA is its poor dissolution and absorption. The present study deals with the dissolution enhancement of CXA by spray drying the CXA in formulated by spraydrying solution containing different hydrophilic polymers like mannitol, sorbitol, poloxamer (pluronic F127), polyvinyl pyrrolidone (PVPK 30), polyethylene glycol (PEG 6000) and the drug (CXA) in different drug polymer ratio of 1:1, 1:2 and 1:3 in methanol. These batches were also prepared with addition of sodium lauryl sulphate (0.0030% w/w). The spraydrying was performed by using spraydryer at 55° C inlet temperature, 45° C outlet temperature, 60% aspiration, 25 1b / inch^2 pressure and 10% feed rate. These spraydried products were characterized for flow & hygroscopicity by measuring angle of repose and wet point. The dissolution profile of CXA spraydried with defferent polymers with and without SLS was also performed by using USP APPARATUS II in 900ml 0.1 N HCL at 50 rpm for 120 min and compared with CXA spraydried alone and marketed preparation. The CXA spraydried with polymers and SLS showed the angle of repose (23-28°) and wet point (15-17% v/w) which was less than the angle repose (49.40%) and wet point (20.70% v/w) of CXA spray dried alone. In dissolution profile study, the highest percentage drug released (99.15%) was observed in case of CXA spraydried with mannitol (1:3 ratio) containing SLS, followed by 99.02% with sorbitol (1:3 ratio) containing SLS and 98.98% with PVPK30 containing SLS. The percentage drug released of CXA spraydried alone and marketed prepation was found 88.89% and 90.11% respectively. It is concluded that the CXA spraydried with polymers and SLS shows good flowability, wettability than CAX spraydried alone and better percentage drug released than drug spraydried alone and marketed preparation.

AP 106 Enteric coating of rabeprazole sodium using a novel dry coating technique

T. Mahesh Kumar, Sangeeta V Chhabada*, Mausami U Shukla, Tushar K. Vyas and Sampad Bhattacharya

Research Division, Formulation and Development Lab., Alembic Ltd., Vadodara 390 003

Coating is a very commonly applied technology to modify/improve the properties of materials. This is typically done by wet chemistry. An innovative method to replace the wet coating process is to directly coat fine particles on target particles. An attempt was made to perform the dry coating technology for enteric coating the rabeprazole, a drug used for the prophylaxis and treatment of ulcerative gastro-esophageal reflux disease (GERD), duodenal ulcers & pathological hypersecretory conditions. This method involves direct feeding of a coating polymer, and simultaneous spraying of the plasticizer to coat the drug. Hydroxy propyl methyl cellulose acetate

succinate (HPMCAS) was used as the coating polymer, and triethyl citrate and acetylated monoglyceride was used in combination for plasticization. Curing of the polymer was done by spraying a small quantity of (2-6%) water or hydroxy propyl methyl cellulose (HPMC) solution, followed by heating of the polymer. Coated tablets of rabeprazole sodium were evaluated for gastric resistance, coating efficiency and stability. The results suggest that this technique be well proven to coat rabeprazole tablets, having sufficient gastric resistance and reduction of processing time and may be suitable for commercial scale up. As the polymer coating powder directly applied to the rabeprazole tablets to form enteric film, the coating time was considerably reduced, and preparation of coating solution is not necessary. It is concluded that this novel approach for the enteric coating of rabeprazole sodium may overcome the limitations of conventional wet coating method including, use of solvent (environmental pollution), low productivity due to low polymer concentration with long coating time and difficulty of applying to water-sensitive drugs.

AP 107 Transmucosal delivery of prochlorperazine maleate using bioadhesive polymers

T. Mahesh Kumar, Mausami U Shukla, Sangeeta V Chhabada, Tushar K Vyas* and Sampad Bhattacharya

Research Division, Formulation and Development Lab., Alembic Ltd., Vadodara 390 003

Transmucosal portion of oral mucosa is an ideal surface for the placement of retentive delivery system such as buccal patches since it contains a large expanse of smooth and immobile tissues. Buccal mucosal bioadhesive patches are a novel external preparation that can render an effective and safe treatment. Absorption of therapeutic agents from oral mucosa eliminates the problems of premature drug degradation within the gastrointestinal tract, as well as active loss due to first pass hepatic metabolism. A more rationale antiemetic drug prochlorperazine maleate (PCP), related to interference with dopaminergic transmission to exert action on CTZ, has been taken as a model candidate. The buccal patches of prochlorperazine maleate were prepared by casting the film and drying. For the preparation of multilayered film, various polymers including natural and synthetic were used at appropriate concentrations. The prepared patches were evaluated for the effects of various polymer combinations on drug release, thickness of the film, peeling strength, residence time of device on the mucosal surface before complete erosion. The results suggested that the natural polymer based combinations (xanthum gum and sodium alginate) shows good adhesiveness but in vitro release was unsatisfactory. While, the adhesiveness and stiffness was acceptable in the case of cellulose based polymer combinations (HPMC, HPC and HEC) but elasticity and dissolution results were not satisfactory. The appearance, mouthfeel, physical acceptance and dissolution release profile were found to be better in case of polyvinyl acetate (PVA-120) based formulation. Also, the stiffness and elasticity characteristics are in balance, which gives more acceptability of this formulation. It was concluded that selection of polymers is more necessary to design buccal patches and this delivery system is more convenient and effective for mucosal delivery of prochlorperazine maleate.

AP 108 Interaction studies of mucoadhesive biopolymers with mucous membrane

Amit J. Raval*, Manish Umrethia,Abhay Goti, Hitesh Dodiya, R.S.R Murthy

New Drug Delivery System Laboratory, Pharmacy Department , Donor's Plaza, The M.S.Uni. of Baroda, Fatehgunj, Vadodara-2

Ketoconazole, an antifungal drug, is widely used in various fungal infections and in treatment of oral candidiasis like infection in mouth, teeth, tongue and other fungal diseases. It is available as an oral tablet formulation. Because of lower bioavailability and biological half-life, frequent dosing is required. The present study deals with the interaction studies of mucoadhesive biopolymers with mucous membrane and selection of best combination of biopolymers and development of Ketoconazole buccal disc formulation that can overcome mentioned drawbacks of conventional Ketoconazole formulation. In experimental studies, different biopolymers like Eudragit RS-100, Carbopol 934P, and Hydroxyl Propyl Methyl Cellulose (HPMC) K-15, Chitosan were selected and polymer discs were formulated by compressing physical mixtures of biopolymers alone and in combination. They were characterized by measuring bioadhesive strength, mucoadhesive strength and tensile strength. Combination of Eudragit RS-100 + HPMC K-15 (1:2), Carbopol 934P + Chitosan (1:2), Eudragit RS-100+Carbopol 934P (1:2) showed better bio-adhesive strength, mucoadhesive strength as well as tensile strength. The selected model drug, Ketoconazole, incorporated in basis containing polymers three combinations. In vitro dissolution studies, one-way and two-way diffusion studies are performed further selected with best bioadhesion and mucoadhesions were carried out on buccal mucosa of sheep by using Franz diffusion cell. The % drug release in one way and two-way diffusion studies were measured.

AP 109 Studies in formulation and evaluation of mucoadhesive buccal film

Parth Parikh*, Vimal Kaneria, Manish Umrethia, R.K.Parikh

L M College of Pharmacy, University Road, Navrangpura, Ahmedabad - 9

The oral cavity is easily accessible for self-medication and the buccal route is subject of growing interest because the absorption of therapeutic compound from the oral mucosa provides direct entry of the drug into the systemic circulation, therefore, avoiding the first-pass metabolism and gastrointestinal drug degradation. This paper describes the preparation of new buccal bilayered device comprising a drug containing mucoadhesive layer and a drug free backing layer. Bilayered films were produced by casting-solvent evaporation technique. The mucoadhesive layer was composed of a mixture of drug and Chitosan with Carbopol and an anionic cross-linking polymer and plasticizer and drug free backing layer. The prepared films were evaluated for the drug release using salbutamol sulphate as model drug, bioadhesion time, hydration ratio and other physical parameters. The blended film prepared by incorporating Carbopol 940 and Sodium alginate to Chitosan showed the controlled release of drug up to 6 hr. Improvement in bioadhesion time was also noted after incorporation of Carbopol 940. The blend film showed higher water uptake that Chitosan film. Incorporation Carbopol 940 further increased the water uptake capacity of the film. It can be concluded that the prepared film demonstrated potential for the use in controlled delivery of drugs to the oral buccal mucosa for a prolonged period of time.

AP 110 Enhancement of bioavailability of sustained release product of Nifedipine

Hemal Tandel*, Ambikanandan Misra

Pharmacy Department, Faculty of Technology & Engineering, Kalabhavan, M.S.University of Baroda, Gujarat, India.

Nifedipine is a calcium channel blocker, practically insoluble in water & aqueous fluids and exhibits poor dissolution rate & whose oral bioavailability is very low. The aim of this study was to enhance the bioavailability of Nifedipine sustained release tablets by investigating the possibility of Nifedipine complexation with α-cyclodextrin & feasibility of employing Nifedipine-α cyclodextrin inclusion complex in the design of sustained release tablets. Sustained release tablets of Nifedipine available in market show high variation in in-vitro dissolution & bioavailability within/among sustained release tablets of different companies. The drug was complexed with cyclodextrin to decrease differences in dissolution behaviour of drug. It is also expected that increase in bioavailability were lead to decrease in dose, side-effect & probably the cost of drug. In this work, complexation of Nifedipine with α-cyclodextrin (αCD) was tried to improve its solubility, dissolution rate & bioavailability. The phase solubility study was performed to investigate the stability of Nifedipine – αCD complexes. The phase solubility diagrams of Nifedipine-âCD can be classified as type A_L according to Higuchi and Connors. The increase in solubility was due to the formation of a 1:1 complex. The apparent solubility constant (Kc) obtained from the slope of the linear phase solubility diagram indicated that the N-αCD complexes formed are adequately stable. The solid inclusion complexes of N-αCD were prepared in 1:0.5, 1:1, 1:2, 1:3 ratios by slurry method. The aqueous solubility of Nifedipine was increased linearly as a function of concentration of â-cyclodextrin. The solubility & dissolution rate of Nifedipine were markedly enhanced by complexation with α-CD, Nifedipine –αCD (1:3) complex gave highest enhancement in the dissolution rate of Nifedipine. In-vitro dissolution study of sustained release tablets formulated with Nifedipine alone gave very poor dissolution rate, whereas those formulated employing Nifedipine-â-CD complexes gave slow controlled & complete release spread over a period of twelve hour than Nifedipine itself. The result of this study suggested that the complexation of Nifedipine with α-CD improves its solubility, dissolution & bioavailability characteristics in a sustained release dosage form.

AP 111 pH-responsive poly (acrylamide-c-maleic acid) hydrogels for colon specific delivery

M. Narender Reddy[a]*, K.P.R. Chowdary[b] and P.V. Diwan[a]

a. Pharmacology Division, Indian Institute of Chemical Technology, Hyderabad 500 007, India

b. Department of Pharmaceutical Sciences, College of Engineering, Andhra University, Viskhapatnam 530 003, India,

The present paper describes the synthesis and characterization of pH sensitive poymeric hydrogel systems designed for colon targeting. Hydrogels composed of poly (acrylamide-co-maleic acid) were synthesized and loaded with a model drug diltiazem hydrochloride (antihypertensive) and their release studies were performed in both the simulated gastric and intestinal pH conditions. The hydrogels have been characterized by equilibrium degree of swelling and mechanical strength. Parameters such as the drug loading method, the initial drug loading concentration, they hydrogel feed composition, degree of substitution, and size of the hydrogel were investigated. The amount of the drug loaded into the hydrogel affected the dynamic release of the encapsulated drug. As expected, the gels showed a complete swelling-dependent mechanism, which was further supported by the similar morphology of the swelling and release profiles of the drug loaded sample. On the other hand the swelling osmotic pressure developed between the gels and the external phase, due to loading of the drug by equilibration of the gels in the alkaline drug solution, plays an effective role in governing the swelling and release profiles.

AP 112 Mixed micellar solubilization of amphotericin B

Sachin Naik* Ambikanandan Misra.

Pharmacy Department, Faculty of Technology & Engineering, Kalabhavan, MS University, Baroda, Gujarat, India.

The objective of this study is to solubilize Amphotericin B(Amp B) by employing the mixed micelle technique.. Bile salt (BS) and Soya Phosphotidylcholine (PC) combined physiologically to form mixed micelles (MM) which aid the solubilization of water insoluble drug molecules. The mixed micellar formulation has been found to be increasing the solubility of water insoluble drugs. The introduction of BS/PC-MM in pharmaceutical formulations as a vehicle for drugs, which are insoluble in water, has eliminated many disadvantages associated with the other co solvents often used. A bile salt solution was prepared initially by dissolving the required amount of bile salt in distilled water (DW) to form a concentrate as per the experimental design and aliquotted according to experimental requirements. Lecithin was added to the bile salt solution and the solution made up to volume. Amp-B was added in excess to each mixed micelle formulation and sonicated to aid solubilization of the drug. The suspensions were centrifuged prior to analysis. The mixed miceller formulation were evaluated for solubility, particle size distribution, transparency, %drug entrapment, viscosity, critical micelle concentration (CMC), optical microscopy, in vitro drug release by using dialysis membrane, minimum inhibitory concentration (MIC) and hemolytic activity. Solubilizing power of the MM formulation appears to increase with the increasing lecithin concentration, and the molar ratio of lecithin to bile salt. BS/PC-MM delivery system may provide a useful vehicle to solubilize water insoluble compound such as Amphotericin B and significantly improving its bioavailability.

AP 113 Preparation and evaluation of the polyelectrolyte complex (PEC) film containing clotrimazole

Bhupendra Prajapati*, Krutika Sawant, Yogesh Raichandani, and Ashish Mehta.

Pharmacy Dept, Faculty of Technology and Engineering, The M.S.University of Baroda,Vadodara-390001

Clotrimazole is used widely for treatment of cutaneous candidiasis, pityriasis, and mild to moderate ringworm of glaborous skin and vulvo vaginal candidiasis. Cream base formulation requires multiple applications; the film can solve this problem by giving sustained release of the drug. The aim of present study was to design a formulation of PEC film for transdermal delivery of Clotrimazole. PEC film was prepared using complex coacervates of chitosan with sodium alginate. Different PEC films were formulated using complex coacervation method. Chitosan solution was added drop wise to the 0.7% solution of sodium alginate in distilled water with continuous rapid stirring using propeller stirrer for 30min to get fine and uniform dispersion of the complex coacervate. Viscosity of the supernatant was determined to optimize the ratio of chitosan and sodium alginate in PEC. This fine complex was cast and dried at 60 °C for 24 hrs. The PEC film formulation was optimized with respect to various variable parameters like chitosan: alginate ratio, Stirring speed, drying time and drug: PEC ratio. The optimized level was decided on the basis of extent of complexation, fineness of complex, homogeneity of dispersion, ease of casting of film and film formation. The optimized film were studied for the film thickness, content uniformity, water vapor transmission rate (WVTR), swelling ratio and in-vitro release of clotrimazole. Chitosan to sodium alginate ratio of 1:1.5 showed the same viscosity as the solvent used for preparation. The stirring time was optimized to 30min at 4000rpm. Polyethylene glycol (0.2 ml) was used as plasticizer. In-vitro study of the film prepared from different ratio of drug to PEC (1:1.5, 1:2 and 1:3) showed that as the drug to polymer ratio was increased drug release was sustained and showed Fickian law of diffusion.

AP 114 Cyclosporine loaded solid lipid nanoparticles (SLN)

Jigisha Varia,* Krutika Sawant

Pharmacy Department, Faculty of Technology and Engineering, The M.S.University of Baroda, Vadodara-390002.

Cyclosporine is a highly hydrophobic cyclic oligopeptide, extensively used as immunosuppressant in organ transplant patients and autoimmune diseases. Oral bioavailabilty of cyclosporine is very low due to its poor absorption. Solid lipid nanoparticles (SLN) were prepared to investigate their possibility to increase bioavailability. Lipid based formulations can reduce the inherent limitations of slow and incomplete dissolution of poorly water-soluble drug like cyclosporine. SLN were formulated using glyceryl monostearate (GMS) as lipid and the system was stabilized by using mixture of soya lecithin (SPC) and sodium taurocholate (STC). SLN were prepared by hot homogenization technique, in which crude o/w emulsion of melted GMS homogenized at 15,000 to 20,000 psi for three homogenization cycles. Cyclosporine loaded nanoparticles were evaluated for the particle size, encapsulation efficiency and in vitro drug release. The mean diameter of GMS nanoparticles was found to be 129 nm. The encapsulation efficiency of cyclosporine

in GMS nanoparticles was found to be 89.20%. Differential Scanning Calorimetry (DSC) of glyceryl monostearate and solid lipid nanoparticles containing glyceryl monostearate was performed to investigate the status of the lipid.

AP 115 Preparation and evaluation of fast dissolving tablets of domperidone by sublimation technique

Yogesh H. Raichandani*, Bhupendra G.Prajapati, Ashish K. Mehta, Krutika K. Sawant

Pharmacy Department, Faculty of Engineering and Technology, The M.S.University of Baroda,Vadodara-390002

Incidences of patient noncompliance occur due to difficulty of swallowing solid oral dosage form in geriatric, pediatric, mentally ill, bed ridden and uncooperative patients. To overcome this difficulty a novel type of tablet dosage form for oral administration called "FAST DISSOLVING TABLETS", which dissolves rapidly in saliva without the need of drinking water, is gaining popularity. Fast dissolving tablets can be made by many techniques like tablet moulding, freeze-drying, sublimation, disintegrant addition and sugar based excipients. The present work involves the use of sublimation technique to develop fast dissolving tablets of domperidone, an anti-emetic agent. In this study,domperidone was mixed with various ratios of pearlitol:menthol. The powder was compressed and menthol was sublimed from the tablets. These tablets were evaluated for size & thickness, hardness, friability, weight variation, wetting time, porosity, assay, invitro & invivo disintegration time and dissolution studies. Based on the hardness, friability, porosity and disintegration time the batch of the pearlitol:menthol ratio of 9:1was found to be the optimized formulation. The optimized formulation has hardness 3 kg/cm^2, friability 0.5%, porosity 23.4%, invitro disintegration time 37±2 seconds and invivo disintegration time 33±3 seconds.

AP 116 Enhancement of bioavailability of water insoluble drug via microemulsion technology

Hitesh D. Dodiya*, Manish Umrethiya, Amit Raval, Abhay Goti, R.S.R.Murthy.

Pharmacy Department, Faculty of Technology and Engineering, Kalabhavan, M.S.University of Baroda, Vadodara. 390 001

Recent research has shown that more than 40% of new molecules have poor aqueous solubility, which has spawned a whole group of technology providers trying to enhance the availability of the drug in the intestinal lumen. Among the different innovative formulation approaches that have been suggested for enhancing lipophillic drug absorption and then clinical efficacy. Lipid based system such as microemulsion are considered as promising solution for improving drug bioavailability. The purpose of this study is to incorporate the Tamoxifen-the nonsteroidal antiestrogenic oestrogenic compound in the microemulsion. The Microemulsion are prepared using Tween-80 as surfactant. Ternary phase diagram has been prepared using titration method. The formulation are evaluated for different optimizing parameter e.g. droplet size (Malvern Mastersizer V Hydro 2000 M), lipid concentration, surfactant concentration, co-surfactant concentration. In-vitro drug diffusion using semipermeable gelatin membrane has taken as response parameter in optimizing study. Physical stability of the microemulsion was studied based on parameter like creaming, cracking and phase seperation. Microemulsions with droplet size 100-150 nm has been successfully prepared. No creaming, cracking and separation of microemulsion was observed during two month of storage.

AP 117 Melt granulation : A novel technique to co-process a pharmaceutical diluent for direct compression

Penumudi Rao and Sunil Jambekhar

Department of Pharmaceutical Sciences, Massachusetts College of Pharmacy and Health Sciences, 179 Longwood Avenue, Boston, MA 02115, U.S.A.

Direct compression method is one of the preferred methods of tablet preparation due to minimum processing steps involved. Direct compression is commonly achieved by using coprocessed diluents, which are prepared by methods such as minigranulation, codrying and spray drying. These coprocessing methods are similar to wet granulation, which involve the addition of a granulating liquid followed by drying. These wet methods of co co-processing increase the cost of preparing the coprocessed diluents. In this research, applicability of melt granulation, as a novel technique, to coprocess a diluent has been studied to reduce the cost associated with wet granulation methods. Melt granulation is a simple, rapid, and less energy consuming method employed to prepare granules. α-lactose monohydrate, which has good flow properties, and α-cyclodextrin, which has good compression properties, were coprocessed in different ratios (75:25 w/w, 60:40 w/w, and 90:10 w/w) by employing melt granulation method. Polyethylene glycol 8000, in different concentrations (5% w/w, 10%w/w, and 15%w/w), was used as a melt granulating agent. Multiple linear regression analysis and one way ANOVA were used to optimize the processing parameters. The optimized coprocessed diluent prepared by melt granulation

method was characterized and compared with the commercially available, commonly used coprocessed diluents such as Ludipress®, Supertab®, Kleptose®, and Cellactose®. The coprcessed diluent with 75:25 ratio of á-lactose monohydrate to â-cyclodextrin showed better flow and compressible charactertics than Cellactose®, Ludipress®. Coprocessing was achieved sucessfully with in 30 minutes.

AP 118

Effect of skin penetration enhancers on the release and skin permeation of bupranolol from reservoir type transdermal delivery systems

R. J. Babu*# and J. K. Pandit

Department of Pharmaceutics, Institute of Technology, Banaras Hindu University, Varanasi, UP - 221 005

#College of Pharmacy and Pharmaceutical Sciences, Florida A and M University, Tallahassee, FL 32307, USA

Bupranolol (BPL), a potent beta-blocker, upon oral administration undergoes extra-ordinary first-pass metabolism (> 90% in humans) and is rapidly eliminated with a half-life of 1.5-2.0 hr. The physicochemical and pharmacokinetic of this drug make it to be suitable for the development of transdermal delivery system (TDS). Reservoir type TDS of BPL was developed using HPC gel reservoir, CoTran™-Polyethylene Film and adhesive, Scotchpak™ Film and Liners. The influence of penetration enhancers such as 2-pyrrolidone (PY), N-methyl-2-pyrrolidone (NMP), hydroxypropyl b-cyclodextrin (HPBCD), partially methylated b-cyclodextrin (PMBCD) and propylene glycol (PG) on the release and skin permeation of BPL was investigated. Excised Wister rat skin, Keshary-Chien type diffusion cells and pH 7.4 phosphate buffered saline were used for skin permeation experiments. The analysis of BPL from the permeation and release samples was carried out according to LeBrun et al (1989). As shown by the release rate constants in the Table, the release of BPL from various TDS were similar and the difference due to different enhancers in the formulation was not significant ($P > 0.05$).

Batch code	Release rate mg/cm²/hr$^{-1/2}$	Permeation rate (mg/cm²/hr)
R6-PE	0.5416±0.025	18.51±1.27
R7-PE	0.6090±0.020	52.06±0.61**
R8-PE	0.5572±0.025	29.24±0.42
R9-PE	0.5262±0.010	37.46±3.67**
R10-PE	0.5921±0.018	47.42±4.92**
R11-PE	0.5364±0.005	26.76±3.23
R12-PE	0.5680±0.003	33.05±1.47*

*P < 0.05, **P<0.001 versus R6

Permeation rates of the devices R7-PE and R8-PE were about 3 and 1.5 fold higher than R6-PE ($P < 0.01$). PY (R7-PE) and MPY (R8-PE) both acted as penetration enhancers even at low concentrations. The permeation rates of devices R9-PE, R10-PE (containing PMbCD and HPbCD as enhancers respectively) was about 2.5 and 2 fold higher than R6-PE (no enhancer, $P < 0.01$). Inclusion of PG in devices R11-PE and R12-PE increased the permeation rate significantly versus R6-PE (no enhancer, $P < 0.05$). Conclusion: TDS can be fabricated by using HPC gel reservoir and CoTran™ microporous polypropylene as rate controlling membrane. The delivery of bupranolol from these devices can produce 4-5 times higher levels than the desired target delivery rate.

BP$_1$ Synthesis and biological evaluation of amino pyrimidines, thio pyrimidines and hydroxy pyrimidines bearing benzofuran

V. Harinadha Babu, P.Senthil Kumar, Fakhruddin Ahmed*.

Department of Pharmaceutical Chemistry, College of Pharmaceutical Sciences, MAHE, Manipal - 576 119.

Benzofuran chalcones were prepared by the reaction of 2-acetyl benzofuran with different aromatic aldehydes in the presence of a strong base. Cyclocondensation of benzofuran chalcones with guanidine hydrochloride, thiourea and urea resulted in the formation of various amino pyrimidines (3a-i), thio pyrimidines (4a-i) and hydroxy pyrimidines (5a-i) respectively. The structures of all the compounds were charecterised on the basis of analytical and spectral data. The compounds were screened for antitumour activity by Brine shrimp bioassay method followed by invivo survival time method using Ehrlich scitic carcinoma.Tumour response was assessed on the basis of median survival time (MST) and percentage treated /control. The test compound were administered intraperitonially at a dose of 100mg/kg weight in the form of suspension using 2% SCMC as suspending agent . Cisplatin was used as standard. Among twenty five compounds, compounds 3b and 3d showed significant antitumour activity

All the compounds were also screened for antibacterial and antifungal activity at a concentration of 500ug / ml and 100ug /ml against S.aureus, B.subtilis, *P.aeruginosa, E.coli, Klebsiella* and *C.albicans*. All the synthesized compounds exhibited highly significant antifungal and antibacterial activity. While compounds 3f, 3i, 4a, 4f, 4g and 4h have showed moderate activity against *P.aeruginosa*, compounds 4h, 4i, 5a, 5h and 5i showed highest activity against *C.albicans*. Ampicillin (1000 units), gentamycin (1000 units) and amphotericin B (100 units) were used as standards for antibacterial and antifungal activity respectively.

BP$_2$ Computer aided design of poly (ADP-ribose) polymerase (PARP) inhibitors : molecular field analysis and receptor surface analysis

P. Narayana Raju*, M. Swapna[1], B. Srikanth, M.E.B. Rao and K. Prakash

Roland Institute of Pharmaceutical Sciences, Berhampur (Gm) - 760 010, ORISSA.

1. College of Veterinary Sciences, A.N.G.R. Agriculture University, Hyderabad.

Poly (ADP-ribose) polymerase is a chromatin-bound nuclear enzyme involved in various physiological functions related to genomic repairs. It involves in DNA replication and repair, cellular proliferation and differentiation and apoptosis. PARP selectively activated by DNA strand breaks, uses nicotinamide dinucleotide (NAD) as substrate and catalyzes the poly-ADP ribosilation of a variety of proteins, including caspases, topoisomerases, histones and PARP itself.

Because of its involvement in process related to DNA damages, PARP has been considered as a suitable target for antitumoral drugs. PARP inhibitors for which homogeneous biological values are available were collected from the literature. The present study involves the 3D QSAR of 45 PARP inhibitors includes Molecular Field Analysis (MFA), Receptor Surface Analysis (RSA) and the property of each molecule was predicted. This study quantifies the relationship between structure and biological data and useful for optimizing the groups those modulate the potency of molecule. All the molecules were aligned in cerius^2 software using SGI (Silicon Graphics Inc.) system. The QSAR model was generated using RSA for aligned molecules. The RSA yield a r^2_{cv} 0.914 and conventional correlation coefficient (r^2) of 0.918. The QSAR model generated using MFA and produced r^2_{cv} 0.905 and a conventional correlation coefficient (r^2) 0f 0.919.

In conclusion, the examination of QSAR equations, has allowed us to put forward some of the structural features that may affect the binding of inhibitors. The results here reported can usefully be employed for rational design of novel, potent PARP inhibitors in the search for novel neuroprotective agents.

BP$_3$ QSAR analysis of some 2,3- diaryl benzopyran derivatives as selective cyclooxygenase – 2 inhibitors"

S. Prasanna[1]* and S.C Chaturvedi[2].

1. School of Pharmacy, DAVV, Indore
2. RGPV, Bhopal.

Quantitative Structure Activity Relationship (QSAR) analysis has been performed in a series of 2, 3 diaryl Benzopyran derivatives acting as selective COX-2 inhibitors. All the computational works were performed on the Molecular Operating Environment (MOE), supplied by the Chemical Computing Group. The molecules were sketched using the molecule builder and each structure was subjected to energy minimization technique using sequential Steepest Descent, Conjugate Gradient and Truncated Newton Raphson methods. Conformational search was done using stochastic approach and various 2D and 3D descriptors were calculated for each most stable

conformer. Pruning of the descriptors was aided by QSAR contingency analysis. The models (regression equations) generated were statistically significant with r = (0.80 - 0.84), $F_{(3, 22)}$ = (13.1 - 17.8), s = (0.27 - 0.31) for a training set of 26 compounds.

QSAR investigations resulted in the exploration of some 3D descriptors like density, std_dim2 best describing the biological activity. SlogP_VSA1 is a subdivided surface area 2D molecular descriptor based on an approximate accessible Vander waal's surface area calculated for each atom. std_dim2 is the square root of the second largest eigen value of the covariance matrix of the atomic coordinates. The negative slope of the atomic connectivity index (order 0) chio_0 suggests an unfavorable effect on the biological activity. The cross validation was performed using Leave One Out (LOO) method. The predictability of the models was good (q^2 ranging from 0.49 - 0.63). Alignment of the compounds was accomplished with the use of MOE-Flex Align. All the descriptors used in the models were found to be orthogonal as exemplified by the correlation matrix and variance inflation factor for simple and multiple collinearity problems respectively.

BP 4 Solution and solid phase combinatorial synthesis of benzothiazole libraries

Asit K. Chakraborti, Gurmeet Kaur and Kirtikumar B. Jadhav*

Department of Medicinal Chemistry, National Institute of Pharmaceutical Education & Research (NIPER), Sector 67, S. A. S. Nagar,Punjab 160062, India.

Combinatorial organic synthesis has emerged as an important tool for the generation of libraries of pharmacologically attractive molecules. The benzothiazole moiety constitutes a versatile pharmacophore exhibiting a broad spectrum of biological activities such as potent and selective antitumor activity, antimicrobial activity, wide spectrum Ca^{2+} channel antagonistic activity and inhibitory action against several enzymes such as monoamine oxidase, lipoxygenase, acetylcholinesterase, thrombin, collagenase and aldose reductase, H^+-K^+ ATPase and carbonic anhydrase. Therefore, the synthesis of benzothiazoles has become of considerable interest to organic and medicinal chemist for many years.

We have recently developed efficient methodologies for conversion of aldehydes to nitriles[1] and realised that this methodology offers a strategy for in situ generation of 'activated' nitriles and should provide handle for further synthetic manipulation. Herein, we report that aldehydes are converted into benzothiazole in a one pot reaction by the treatment with $NH_2OH.HCl$ and 2-aminothiophenol in NMP. The methodology has been extended to generate small combinatorial libraries of benzothiazoles in solution as well as solid phase with the help of the self developed 'demand based'[2] and 'single electron transfer mediated'[3] thiolate anion generation strategies.

The studies under the present investigation have enabled us to achieve the major objectives in terms of development of: (i) methodology for the synthesis of benzothiazoles, (ii) analytical protocols (HPLC, APCIMS and LCMS) to identify the constituents of the benzothiazole libraries, (iii) novel methodology to liberate benzothiazoles from the solid support, and (iv) synthesis of solution and solid phase benzothiazole libraries and will be helpful in optimisation of lead benzothiazole molecule for focused biological activities.

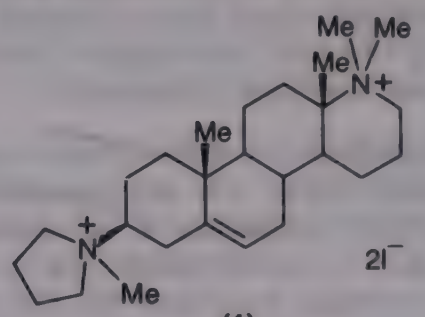
BP 5 Synthesis and biological activity of some chandonium analogues

Poonam Piplani[a], Maninder Minu[a]*, VibhaTiwari[a], Dharam Paul Jindal[a] and H. Fajrak[b], C. Prior[b], I. G. Marshall[b]

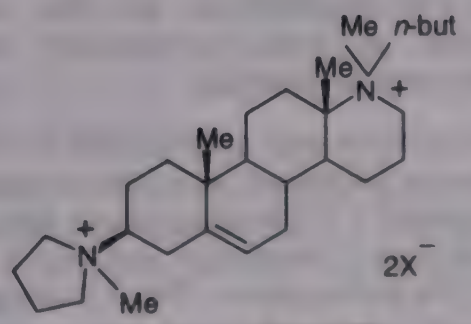
a. University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh, India 160014;

b. Department of Physiology and Pharmacology, University of Strathclyde, Royal College, Glasgow, GI IXW, Scotland, U.K.

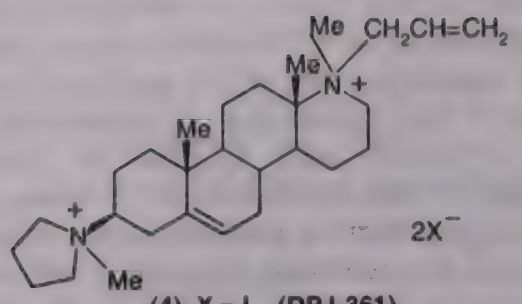
Chandonium iodide, 17a-methyl-3b-pyrrolidino-17a-aza-D-homo-5-androstene dimethiodide (1) synthesized at University Institute of Pharmaceutical Sciences, P.U., Chandigarh is a potent nondepolarizing neuromuscular blocking agent having rapid onset and short duration of action with no ganglion blocking activity. This compound exhibits some cardiovascular effects due to its vagolytic activity. Therefore for optimizing the muscle relaxant activity and eliminating the vagolytic and ganglion blocking effects, it was considered worthwhile to introduce bulkier groups at position 17a to study the effect of increased lipophilicity and size of N-substituents on the neuromuscular blocking mode of action. Here we report the 17a-N-butyl and 17a-N-allyl analogues of chandonium in both iodide and bromide salts (2-5).



(1)



(2) X = I (DPJ-357)
(3) X = Br (DPJ-390)



(4) X = I (DPJ-361)
(5) X = Br (DPJ-391)

Dehydroepiandrosterone acetate after oximation was subjected to Beckmann's rearrangement to obtain the lactam. The lactam after sodium pentanol reduction was subjected to oppenauer oxidation. The a,b-unsaturated ketone was treated with n-butyl iodide and allyl bromide respectively and the products were reacted with pyrrolidine to get the respective enamines. Subsequent sodium borohydride reduction and quaternization with methyl iodide gave the bisquaternary compounds 2 (DPJ-357) and 4 (DPJ-361) respectively. Similarly bromide derivatives 3 (DPJ-390) and 5 (DPJ-391) have also been prepared.

After pharmacological investigations all the synthesized compounds have been found to be highly potent neuromuscular blocking agents. The two 17a-N-butyl compounds 2 (DPJ-357) and 3 (DPJ-390) represent the most powerful neuromuscular blocking drugs discovered to date.

BP$_6$ Synthesis of dexrazoxane and its analogs

Viswanathan C.L., Sakpal V. S. & Lokhande T.N.*

Bombay College of Pharmacy, Santacruz (E), Mumbai-98.

The clinical use of antitumor drugs like doxorubicin, adriamycin is limited due to cumulative dose dependent carditoxicity. The use of dexrazoxane, 4,4'-(1-methyl-1,2-ethanediyl)-bis-(2,6-piperazinedione) as an adjuvant with these drugs reduced cardiotoxicity by chelating the iron and copper and preventing oxidative stress and lipid peroxidation.

Dexrazoxane is a antimetastatic agent due to potent chelating action. It is also cytostatic agent and showed significant *in-vitro* and in vivo antitumor activity against number of tumor types, due to its ability to inhibit DNA synthesis and block the cell division. .

Due to multiplicity of role played by dexrazoxane, it was considered to prepare dexrazoxane and its analogs.

Dexrazoxane was synthesized by treating 1,2-diaminopropane tetraacetic acid with formamide. In the alternate method 1,2-diaminopropane tetraacetic acid was converted to a tetraamide and then cyclized with phenol to give dexrazoxane. The 1,2-diaminopropane tetraacetic acid was synthesized from propane-1,2-diol. Following analogs were also synthesized using the procedure established for dexrazoxane.

4,4'-(1,2-ethanediyl)-bis-(2,6-piperazinedione), trans-4,4'-(1,2-cyclopropanediyl)-bis-(2,6-piperazinedione), 4,4'-(1,2-ethanediyl)-bis-(1-hydroxymethyl-2,6-piperazinedione), 4,4'-(1,2-ethanediyl)-bis-(1-acetoxymethyl-2,6-piperazinedione) and 4,4'-(1-methyl-1,2-ethanediyl)-bis-(1-hydroxymethyl-2,6-piperazinedione) Products were characterized by physical constants and spectral analysis.

The synthesis of dexrazoxane was achieved from simple substrate propane-1,2-diol. The method of cyclisation using phenol as a catalyst was novel and gave good yield. Similarly ethyl carbamate was used for cyclisation of the tetraacetic acid .Number of analogs were also synthesized satisfactorily in good yields.

BP$_7$ VALSTAT : Validation program for quantitative structure activity relationship

A.K. Gupta*, M. Arockia Babu, S.G. Kaskhedikar

Dept. of Pharmacy, S G S I T S 23, Park Road, Indore 452 001

Molecular modelling has been a novel and powerful tool for design of new potent molecules of biological interest and now, scientists are fascinated towards molecular modelling and have found conventional methods of drug development the hard way. To conquer thrust, numbers of research groups independently have developed statistical programs that computers statistical parameters such as correlation coefficient (r), standard error (s), and Fischer test (F). These three parameters are not sufficient for selection and validation of better QSAR models. For this purpose, additional special statistical parameters such as cross-validation squared correlation coefficient (q^2), bootstrapping squared correlation coefficient (BSr^2), randomization test (chance) and outliers should be incorporated. To fulfill this requirement, the VALSTAT program that can run on PC has been developed using C^{++} language. The program reproducibility and accuracy were validated using few reported series of cyclooxygenase-2 (COX-2) inhibitors that included terphenyl, 4,5-diaryl imidazole derivatives. Eqn. 1 and 2 were generated using VALSTAT program and eqn. 1* and 2* have been reported in the literature.

It can be observed that the values of statistical equation obtained using our program are more or less similar to that of reported values. However, the marginal difference in r^2 values is due to rounding up of the data values in the literature.

$$-\log C50 = 1.11(\pm0.21)*ClogP + 0.45(\pm0.14)*Iy - 0.83(\pm0.27)*\sigma^+X - 1.06(\pm0.24)*CMR + 12.46(\pm1.93)$$

$n=24,\ r^2=0.907,\ std=0.164,\ F=46.568,\ BSr^2=0.905,\ chance<0.01,\ q^2=0.842$ .....(Eqn.1)

$$-\log IC_{50} = 1.12(\pm0.20)*ClogP + 0.45(\pm0.14)*Iy - 0.83(\pm0.27)*\sigma^+X - 1.06(\pm0.24)*CMR + 12.91(\pm1.91)$$

n=24, r^2=0.909, std=0.164, q^2=0.845.....(Eqn.1*)

$-\log C_{50}$=1.42(±0.39)*ClogP - 4.62 (±1.84)* MgVol - 0.79 (±0.48)*BI_{x2} + 3.75 (±3.97)

n=15, r^2=0.886, std=0.212, F=28.415, BSr^2=0.899, chance<0.01, q^2=0.798.....(Eqn.2)

$-\log IC_{50}$=1.45(±0.40)*ClogP-4.67 (±1.84)*MgVol-0.78 (±0.48)*BI_{x2}+3.79(±3.94)

n=15, r^2=0.885, std=0.212, q^2=0.798.....(Eqn.2*)

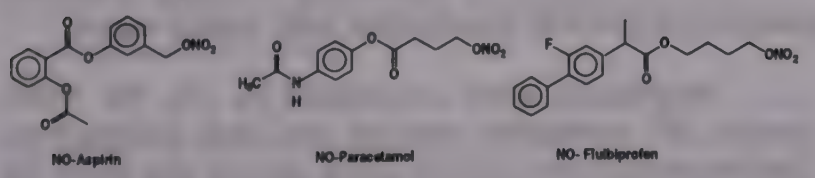
In addition to Hansch approach, both the series were subjected to Fujita-Ban QSAR approach using multiple regression analysis. It was found that the developed program gives matrix as well. It was also intended to help researcher in the field of QSAR to carry out regression analysis. The VALSTAT program will rationally give the way to develop new molecue by selecting better model from the population of the different QSAR models.

BP 8 Nitric oxide releasing drugs: Molecular modeling studies

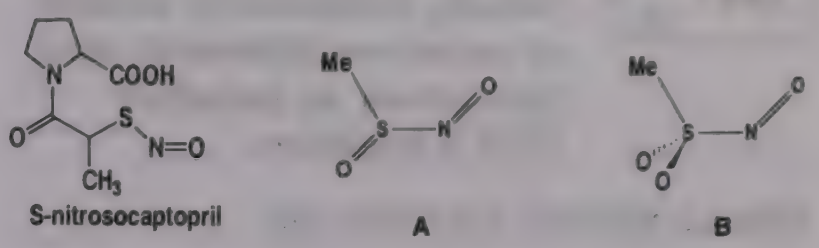
P. Senthil Kumar* and P. V. Bharatam

Department of Medicinal Chemistry, National Institute of Pharmaceutical Education & Research, Sector 67, S. A. S. Nagar (Mohali) – 160 062, India.

Research over the past 20 years has identified endogenous nitric oxide (NO) as a key messenger molecule in the cardiovascular, nervous and immune systems. Recent development in NO donor drug research is the hybridization of NO donor moieties with currently available cardiovascular drugs. The first example of such a compound was S-Nitrosocaptopril; other compounds such as NO-aspirin, NO-paracetamol, NO-flurbiprofen and NO-steroids of nitric oxide releasing agents are presently being developed.



Nitrosothiols release nitric oxide enhanced by thiol, light, metal ions and unknown enzymes. We have performed quantum chemical studies on some of the NO releasing systems to understand the electronic structure reactivity and drug action. S-Nitrosothiols (RSNO) is less stable compounds because of very weak S-N bond dissociation energy. We have extended these studies to the singly oxidized and doubly oxidized nitrosothiols (A, B). The S-N rotational barriers, S-N bond dissociation energies, second order interaction have been estimated using ab initio HF/6-31+G*, B3LYP/6-31+G* and MP2(full)/6-31+G* levels. The results indicate that NO release becomes much more facile that upon single and double oxidation at sulfur. Hence a drug metabolic path involving S-oxide formation favors NO release in S-Nitrosocaptopril.



BP 9 Synthesis and anti-inflamtory activity of 2-(Alkylamino)-5-substituted-4-methyl-thiophene-3-Carboxylic acid methyl ester

Kamala K Vasu, Ajay Pillai, Rathod P.D., Swapnil Yerande*, Harish Padh & V. Sudarsanam.

B. V. Patel Pharmaceutical Education Research and Development Centre Thaltej-Gandhinagar Highway Thaltej Ahmedabad- 380 054 Gujarat India

Lack of efficacy in arresting or preventing disease progression in chronic inflammatory conditions is still a grave unmet medical need in this therapeutic area. The design strategy of molecules under study, were based on a Roche candidate (Ro-31-3948), Romazarit (2-[{2-(4-chlorophenyl)-4-methyl-5-oxazolyl} methoxy]-2-methyl propionic acid sodium salt, which had exhibited interesting anti-inflammatory activity. It was withdrawn from the phase II clinical trials due to the adverse effects (bladder tumor) that emerged in chronic toxicity studies. The toxicity produced by Romazarit could be due to the formation of aa-methyl acrylic acid by metabolic degradation of the compound probable cause of bladder tumor formation.

In the present study we have made thiophene analogues of Romazarit and changed the side chain of Romazarit with oxo propionic acid esters, which is less liable to form these toxic substances. These oxo propionic acid side chains is having drug like feature and have proven to be safe in III rd generation of cephalosporin.

Tetra substituted thiophenes where prepared by method of Rajappa et al. The structured of the synthesized compounds were established by IR, NMR, MASS & C, H, N analysis.

Compounds were tested at the dose level 100mg/kg, p.o. for the anti-inflammatory activity in the carrageenan induced rat paw edema test. Sprague-Dawley (Male/Female) rats weighing 150-250g were used for the edema test.

2-ethylamino-5-(2-ethoxycarbonyl-2-acetyl)-4-methyl-thiophene-3-carboxylic acid methyl ester (AP59) showed 64 % inhibition was the most active compound of the series.

BP 10 Quantitatative structure-activity relationship studies of some meclofenamic acid derivatives as selective COX-2 Inhibitors

Tamanna Mehtani*, S.C.Chaturvedi

Department of Pharmacy, SGSITS, Indore (MP), India.

The use of quantitative structure activity relationships (QSAR) since its advent has become increasingly helpful in understanding many aspects of chemical-biological interactions in drug research. This approach was utilized to explain the relationship of structure with biological activity of Selective COX-2 inhibitors. The enormity of the COX-2 discovery is reflected in the unprecedented speed at which research laboratories have sought to validate its clinical implications. Presented herein is a series of 21 derivatives of Meclofenamic Acid with selective COX-2 inhibitory activity utilizing Molecular Operating Environment (MOE) supplied by the Chemical Computing Group. The set of compounds were subjected to energy minimization using MMFF94 as the force field and 191 numerical descriptors were calculated. The best QSAR models were selected for both COX-1 and COX-2 inhibition on the basis of statistical significance. The model selected for COX-2 inhibition revealed density to be the highest positively contributing parameter. Fractional positive polar Vander Waals surface area was found to be the most significant for COX-1 inhibitory activity. The best models were found to be significant above 99%.

COX-2 inhibition:

pIC_{50} = (-2.711191) + (0.678965) Kierflex+ (9.683321) density + (-0.000482) pmiX + (-0.009799) SMR_VSA7

n=21, r=0.828, r^2=0.685, F=6.092, t=2.468, s=0.533, r^2_{cv} = 0.477, r^2_{bs} = 0.730,

s_{press} = 0.643, s_{DEP} = 0.561.

$F_{4, 16}a$, 0.01=5.64

COX-1 inhibition:

pIC_{50} = (6.354428) + (-0.658493) E_ang+ (17.313815) PEOE_VSA_FPPOS+ (0.000981) pmiZ + (-0.080566) vsa_don

n=21, r=0.858, r^2=0.735, F=7.783, t=2.790,s=0.579, r^2_{cv} = 0.395, r^2_{bs} = 0.786,

s_{press} = 0.819, s_{DEP} = 0.715.

$F_{4, 16}a$, 0.01=5.64

The selected models were cross-validated using leave-one out (LOO) and bootstrapping methods. This study revealed the importance of steric bulk for COX-2 inhibitory activity. These results are proved by x-ray crystallographic studies of COX-2 enzyme whose active site is 17-20% larger than that of COX-1.The selected models could be used to design novel Selective COX-2 inhibitors devoid of the side effects shown by conventional NSAIDs.

BP 11 Structural modification of calcium channel blockers as antihypertensive drugs and their structure activity studies

Harish Kumar D.R.*, Dharmarajan T.S.,

*Krupanidhi College of Pharmacy, Sarjapur Road, Koramangala, Bangalore 560 034.

1, 4-dihydropyridines (nifedipine, felodipine) are the calcium channel blockers which are in the forefront for the treatment of hypertension. The objective the study was to prepare 1, 4-dihydropyridine analogues to have better bio-availability, aqueous solubility, chemical stability and higher potency when compared to felodipine (standard). The analogues were synthesized by Hantzsch and modified Hantzsch reactions are :

a.1,4-dihydro-2, 6-dimethyl-4-(3',4',5'-trimethoxyphenyl)-3, 5-pyridine dicarboxylic acid ethyl ester;

b.1, 4-dihydro-2, 6-dinethyl-4-(3',4',5'-trimethoxy phenyl)-3,5-pyridine diamide;

c.1,4-dihydro-2,6-dimethyl-4-(3'-methoxy,4'-hydroxyphenyl))-3,5-pyridine dicarboxylic acid ethyl methyl ester;

d.1,4-dihydro-2, 6-dimethyl-4-(3'-methoxy,4'-benzyloxyphenyl)-3,5-pyridine dicarboxylic acid methyl ester;

e.1,4-dihydro-2, 6-dimethyl-4-(2'-3'-dichloro phenyl)-3,5-pyridine diamide;

f. 1,4-dihydro-2, 6-dimethyl-4-(para methoxy phenyl)-3,5-pyridine dicarboxylic acid methyl ester;

Analogues were confirmed by UV, IR, NMR spectra, MP, elementary analysis and were screened for Calcium antagonist activity using guinea pig ileum by invitro method.

The depolarized (45mM-K^4) Tyrode solution with Zero Calcium was used, with calcium as the stimulant for contractions. The dose responses curve for calcium was taken; the effectiveness of the analogues in reducing the responses of the isolated muscles to an increase in calcium concentration was recorded. The tested analogues with PA_2 value are, a) 7.32, b) 7.08, c) 7.48, d) 7.53, e) 6.99, f) 6.95. Analogues a,c,d was found to be more potent and analogues b, e and f were less active when compared to Felodipine (PA_2 value 7.28).

BP 12 Synthesis and evaluation of fexofenadine anlogues for their antihistaminic activity

Sathish. N. K.* Karvekar. M. D. Ramesh. A. R. and Gopkumar. P

Govt. College of Pharmacy, Bangalore -27

S.A.C. College of Pharmacy, AIMS Campus B.G. Nagar, Karnataka, India - 571448

Various analogues of fexofenadines (I&II) are synthesis by friedel craft acylation and condensation of chemical nuclei such as flouro benzene, 4-benzylidine piperidine and azacyclonol etc. By condensation of 4-chlorobutane [4-isopropyle benzene]-1-one (analog I) and 4-chlorobutane [4-flouro benzene]-1-one (analog II) with azacyclonol and sodium carbonate in toluene at 110 to 120 ^{0}c for 7-8 hrs. The structures of the compounds have been established on the basis of their chemical analysis and spectral data (IR, NMR& UV). The synthesized analogues were screened for their antihistaminic activity by in vitro assay on guinea pig ileum. The analogues showed significant antihistaminic activity by inhibiting the contraction induced by histamine on guinea pig ileum.

BP 13 Microwave Induced synthesis and biological evaluation of some schiff bases of 2-amino-3-(N-chlorophenyl carboxamido)-4,5,6,7 - Tetra hydrobenzo [b] thiophenes

K.S. Manjunatha Shetty*, S.Mohan[1]

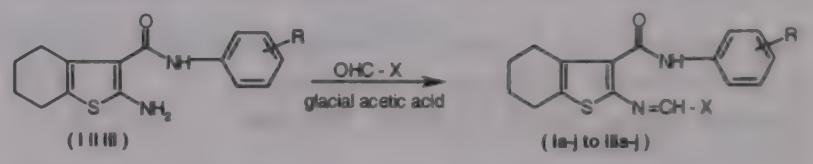
* M.S.Ramaiah Clinical and Bioequivalence/ Bioavailability Center, Gokul Education Foundation, M.S.R.Nagar, Bangalore-560 054.

1. P.E.S.College of Pharmacy, Hanumanth Nagar, Bangalore-560050

Various derivatives of thiophenes and Schiff bases were reported to posses different biological activities like antitubercular, bacteriostatic and antifungal activities. Keeping in view of biological importance of benzo[b]thiophene derivatives and Schiff bases, an attempt was made by us to synthesize thirty new tetrahydrobenzo[b]thiophene Schiff bases using microwave heating and were subjected to antibacterial screening.

2-amino-3-(N-Clorophenyl Carboxamido)-4,5,6,7-Tetrahydro Benzo[b]Thiophenes (I-III) were synthesized by Gewald reaction. Later, the compounds I-III were reacted with ten different substituted arylaldehydes in presence of catalytic amount of glacial acetic acid, produced the new title compounds Ia-j to IIIa-j, via Protonated amino alcohol intermediate with loss of a molecule of water and formation of -N=C- bond. These compounds were characterized by spectral data.

The *in vitro* antibacterial activity of all the synthesized compounds were determined by cup diffusion method using ampicillin as standard. Among the compounds screened, Schiff bases having 4-chloro phenyl substituent at X elicited interesting activity. It is interesting to note that the compounds containing p-chloro substituent at R of the aromatic ring of thieno amido group showed a better antibacterial activity than the active compounds of series I and II.



(I II III) (Ia-j to IIIa-j)

BP 14 Synthesis, characterisation and pharmacological studies of new trisubstituted pyrazolines

P.V.R. Chowdary, Sonia Chawla, Shashikalarani K*

College of Pharmaceutical Sciences, MAHE, Manipal-576119, Karnataka

Due to the interesting activity of various substituted pyrazolines as biological agents, considerable attention has focussed on this class. The pharmaceutical importance of these compounds lies in the fact that they can be effectively used as analgesics, anti-inflammatory, anti-convulsant, insecticidal, herbicidal, anti-tubercular, anti-carcinogenic & anti-diabetic agents.

In the light of these interesting biological activities it appeared of interest to synthesise some new 1,3,5-trisubstituted pyrazolines.

A number of chalcones were prepared by reacting different substituted aromatic aldehydes with acetophenone in ethanolic sodiumhydroxide solution. The chalcones were immediately reacted with isonicotinyl hydrazides in presence of glacial aceticacid to obtain the corresponding 1,3,5-trisubstituted pyrazolines. The synthesised heterocycles were characterised on the basis of physical, chemical tests and spectroscopic data. These compounds were tested for the acute anti-inflammatory activity and anti-oxidant activity using carragenan induced rat paw oedema method & DPPH (Diphenyl Picryl Hydrazyl) radical scavenging method respectively. Evaluation of the compounds revealed remarkable anti-inflammatory activity reflected by their ability to reduce the carragenan induced inflammation in rats and also appreciable anti-oxidant activity.

BP 15 Synthesis and pharmacological evaluation of some novel, potential thiazolidine diones as Type II antidiabetic agents

Y.S. Modhave*, R.K.Gundu, T. Haripriya, V.S. Velingkar.

Department of Pharmaceutical Chemistry, Prin. K.M.Kundnani College of Pharmacy, 47, Dr. R.G. Thadani Marg, Worli Seaface, Mumbai – 400 018.

Diabetes mellitus (Type II diabetes) has been recognized as a metabolic disorder, characterized by hyperglycemia as a result of insulin resistance and impaired secretion since ancient times and today it remains a global health problem with far reaching effects on lives of the patients.

According to WHO estimates, adults with diabetes mellitus in the world are to be increased from 135 million in the year 1995 to 300 million in the year 2025 and current estimates for India are that the number will increase from 22.4 million in the year 2002 to 57 million in the year 2025 and every 5th diabetic in the world would be an Indian. Thus India will continue to be the diabetic capital of the world.

Statistical and epidemiological data clearly show increasing prevalence of diabetes with time. These disturbing features make it important to promote efforts to study more about the diabetes and prevent the disease with newer classes of antidiabetic agents. Hence there is a need for newer, potential and safer antidiabetic agents.

Thiazolidine diones (Glitazones) are relatively novel class of antidiabetics. In the present work, some newer analogues of this class have been synthesized, characterized and evaluated for antidiabetic activity in Alloxan induced diabetic rats.

Experimental Work: -

a. Synthesis of 5-[4-(3-phenyl 2-propionyl) benzyl] thiazolidine 2,4 dione.
b. Preparation of different analogues of the above mentioned lead compound.
c. Structural elucidation of compounds using FTIR and H-NMR.
d. Primary pharmacological screening in Alloxan induced diabetic rats.

Various analogues of thiazolidine 2,4 diones were synthesized and characterized by spectral analysis like FTIR and H-NMR; they were evaluated for its antidiabetic activity, which showed significant reduction in blood sugar level of diabetic rats.

Summary of the results:

a. All newer analogues were obtained in good yields (75-80%)
b. Physical constants were uncorrected.
c. Structural elucidation was performed with the help of FTIR and H-NMR, Elemental analysis etc.
d. Primary pharmacological screening showed reduction in elevated blood sugar level in rats.

BP 16 Synthesis and 5HT antagonist activity of some 7-[3-(substituted amino) propoxyl] -4- methyl-chromen-2-ones

MVL Aparna, *S.H. Bhosale, Nitin Sati, Vikram Veer, K.R Mahadik

Department of Pharmaceutical Chemistry, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune – 411 038.

It is evident from the literature survey that Chromene-2- ones possess diverse pharmacological properties, which include anticoagulant, antihistaminic, antipsychotic and receptor antagonist activity. Based on these finding an attempt was made to synthesize some new chromene-2-ones and were screened for 5HT-antagonist activity.

Thus five different derivatives of chromene-2-one were synthesized. Taking resorcinol and ethylacetoacetate as starting material 7-Hydroxy –4-methyl chromen-2-one was synthesized by reported method. This on treatment with 1-chloro 3-bromopropane in the presence of K_2CO_3 and acetone resulted in the formation of 7-(3-chloro propoxyl) - 4-methyl-chromen-2-one which was further treated with various secondary amines to get a set of five title compounds. The structures of final newly synthesized compounds were confirmed on the basis of TLC, IR and pNMR studies.

All compounds were screened for their serotonergic activity and locomotor activity. All five derivatives inhibited 5HT induced head twitches in albino mice. The 7-[3-(piperidinyl) propoxyl] -4- methyl-chromen-2-one and 7-[3-(1-morpholinyl) propoxyl]- 4-methyl-chromen-2-one inhibited 5HT induced head twitches in mice at the dose of 25mg/Kg (i.p) whereas 7-[3-(diethylamino) propoxyl]- 4- methyl-chromen-2-one, 7-[3-(dibutyl amino) propoxyl] -4- methyl-chromen-2-one & 7-[3-(1-pyrrolidinyl) propoxyl]- 4-methyl-chromen-2-one inhibited head twitches in mice at dose of 50 mg/Kg(i.p). Next all the derivatives showed dose dependent reduction in spontaneous locomotive activity in mice as compared to control.

BP 17 Monomeric ruthenium (II) chelates acts by the induction of apoptosis against human cancer cell lines

R.Suresh[1*], Hira choudhury[1], S. Bhattacharya[1], L.Manikandan[1].

S.S. Karki, Sutapa Chakraborty[2], Madhumita Roy[2], U.K. Mazumder[1] and M. Gupta[1]

1. Department of Pharmaceutical Technology, Jadavpur University, Kolkata

2. Chittaranjan National Cancer Institute, Kolkata.

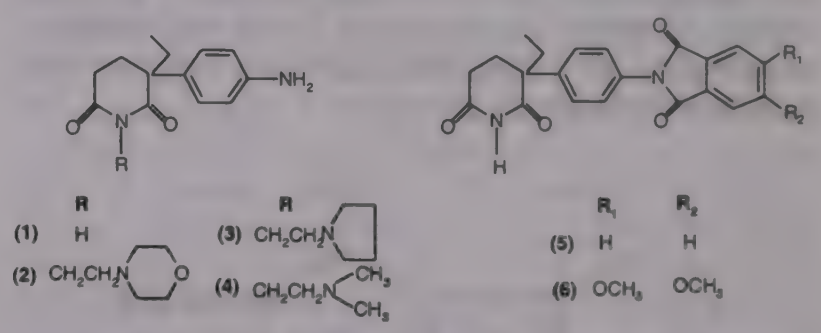
Bis (2,2'-bipyridine) ruthenium (II) complexes containing picolinic acid, acetazolamide and Isatin thiosemicarbazide as ligands have been prepared and fully characterized by elemental analysis, IR, H^1 NMR and FAB Mass spectroscopy. The cytotoxicity of this series of bis (2,2'-bipyridine) ruthenium (II) complexes was tested against cervical epithelial carcinoma (HeLa) and breast adenocarcinoma (MCF-7). Cytotoxicity was assayed by trypan blue dye exclusion assay and 3-(4,5-dimethyl thiazole-2yl)-2,5-diphenyl tetrazolium bromide (MTT) reduction assay. Investigation on cellular morphological changes by fluorescent microscopy, DNA fragmentation study by agarose gel electrophoresis and flow cytometric analysis was also carried out. Thus from the present investigation it can be concluded that these monomeric ruthenium chelates acts by the induction of apoptosis in human cancer cell lines.

BP 18 Synthesis and evaluation of some new aminoglutethimide derivatives for the treatment of mammary carcinoma

Ranju Gupta, Nalin Karkra, Gulshan Kumar*and Dharam Paul Jindal

University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh 160 014

Cancer of the breast is the most common cause of death from cancer in women. Estrogen is thought to be the primary mitogen responsible for the hormone dependent subtype of breast cancer. Blockage of estrogen receptors, inhibition of gonadotropin and inhibiting the biosynthesis of estrogens are the main approaches used for the treatment of breast cancer. Recently aromatase inhibitors, which inhibit the estrogen biosynthesis, have become of interest for the treatment of breast cancer. Aromatase is a cytochrome P_{450} enzyme that catalyzes the conversion of androgens to estrogens. A lot of research is going on for the development of aromatase inhibitors and efforts are being made to promote these as first line agents for the treatment of matastatic breast cancer. Aminoglutethimide (1), the first clinically used aromatase inhibitor, had been the backbone of antiaromatase therapy for the last three decades. Despite high potency, overall toxicity and non-selectivity of aminoglutethimide, limits its usefulness and there is a need for better compounds. A number of aminoglutethimide derivatives have been synthesized in our laboratory to get more selective and less toxic aromatase inhibitors.



For this purpose aminoglutethimide was made to react with hydrochlorides of various haloalkylamines in acetone under anhydrous conditions to obtain 2-4 as oily residues which could not be crystallized and the compounds were characterized as their hydrochloride salts. Phthalimido (5) and dimethoxyphthalimido (6) derivatives of aminoglutethimide have also been prepared to find out the importance of free amino group for anticancer activity. The structures of the newly synthesized compounds were established using various spectral analysis.These compounds have been evaluated for their antineoplastic activity at National Cancer Institute, Bethesda, USA. Unfortunately the compounds did not show statistically significant activity for further studies. The aromatase inhibitory activity of the compounds 2-4 has been carried out at Universtat des Saarlands, Germany. Aminoglutethimide derivatives 2 and 4 have exhibited moderate inhibitory activity against aromatase enzyme.

BP 19 Microwave promoted synthesis and antimicrobial activity of some new 3-N-[(substituted aryl)-methylene]-Imino-2-methyl-5,6-tetramethylene thieno-[2,3-*d*]-pyrimidin-4(3H)-ones

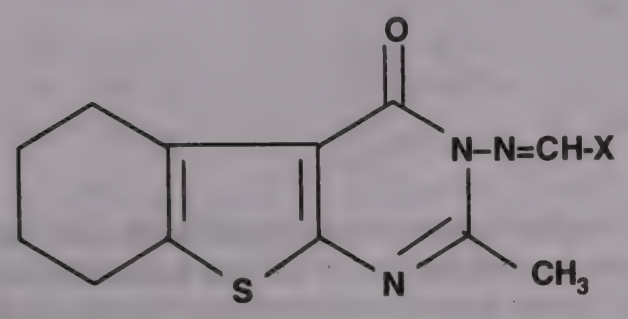
J. Saravanan*, S. Mohan[1]

*M.S. Ramaiah College of Pharmacy, M.S.R.I.T. Post, Bangalore 560 054.

1. PES College of Pharmacy, Hanumanthanagar, Bangalore 560 050

Pyrimidine is a unique molecule. The applications of pyrimidine and its derivatives in chemotherapy are of versatile character. A number of thiophenes such as substituted thiophenes and

condensed thiophenes were also reported to posses antibacterial & antifungal activity. In view of these observations we have planned our synthetic sequence of reactions leading to the preparation of new compounds with 2-methyl-3-N-amino-5, 6-tetramethylene thieno-[2,3-*d*]-pyrimidin-4-one (3) as basic nucleus. Later the compound 3 on treatment with twelve different aryl aldehydes gave the desired compounds (3a-l) of this series. The twelve new compounds were characterized by spectral data and were subjected to anti microbial screening against four bacteria and three fungi by agar plate diffusion method using ampicillin & miconozole as standards. All the compounds exhibited anti microbial activity. Of which, the compound 3f with p-chlorophenyl substitutent at X exhibited significant anti microbial activity comparable to standards.



{ 3 a-l }

BP 20 Synthesis and biological evaluation of some isoxazole derivatives bearing benzofuran

V. Harinadha Babu, Kunthal Manna, Sini Susan Joseph*, K.K.Srinivasan.

College of Pharmaceutical Sciences, MAHE, Manipal-576119, Karnataka.

Benzofuran chalcones (2a -n) were prepared by the reaction of 2 - acetyl benzofuran (1) with different aromatic aldehydes in the presence of strong base. Cyclocondensation of benzofuran chalcones with hydroxylamine hydrochloride resulted in the formation of various benzofuran isoxazoles (3a - n).The structures of (2a - n) and (3a - n) were characterised on the basis of analytical and spectral data. The synthesised compounds were screened for antitubercular, antimicrobial and antiinflammatory activities.

Antitubercular activity was studied against M. tuberculosis H_{37} Rv strain at 1mg, 10mg and 100mg per ml concentrations. INH and Rifampicin were used as standards.The compounds 3j, 3m and 3n were found to possess antitubercular activity at 10m g/ml concentration which is comparable with that of the standard drugs. All the compounds were studied for antibacterial and antifungal activities at a concentration of 500m g/ml and 100 mg/ml against *E.coli, S.aureus, B.subtilis, P.aeruginosa, S.typhi* (antibacterial) and candida albicans (antifungal) .Compounds 3g and 3j have showed MIC at less than 1.25m g concentration and 3m showed MIC at 125m g concentration against *B.subtilis*.The compounds were also studied for antiinflammatory activity by carrageenan - induced paw oedema method in albino rat. None of the compounds have showed significant antiinflammatory activity against the standard drug Ibuprofen.

BP 21 Synthesis, characterisation, anti-Inflammatory and anti-oxidant activity of 1,3,5 trisubstituted pyrazolines

P.V.R.Chawdary, Sonia Chawla, Shailesh G. Jawarkar*

Department of Pharmaceutical Chemistry, College of Pharmaceutical sciences, MAHE, Manipal-576119

Due to interesting activity of various substituted pyrazolines as biological agents, considerable attention has focussed on this class. The pharmaceutical importance of these compounds lies in the fact that they can be effectively used as analgesic, anti-inflammatory, anti-convulsant, insecticidal, herbicidal, anti-tubercular, anti-carcinogenic and antidiabetic agents.

The reactive intermediate chalcones involved in their synthesis also exhibits various biological activities.

The ability of Indole derivatives to exhibit anti-inflammatory, anti-microbial, and anti-fungal activities prompted the selection of Indole as starting compound.

In the light of these interesting biological activities, it appeared of interest to synthesise some new 1,3,5-trisubstituted pyrazolines.

Indole 3-aldehyde prepared by Vilsemier Haack reaction was reacted with 4-substituted acetophenones in ethanolic sodium hydroxide to obtain chalcones, which were condensed with phenyl hydrazine in presence of cyclizing agent glacial acetic acid to obtain 1,3,5-trisubstituted pyrazolines. The synthesised compounds were characterised by elemental, IR, PMR, Mass spectral analysis and were supported by chemical and physical data viz. Rf values melting point differences.

A number of chalcones were prepared by reacting Indole-3-aldehyde, prepared by Vilsemeir Haack reaction with 4-substituted acetophenones in ethanolic sodium hydroxide solution. These chalcones were immediately reacted with phenyl hydrazine in presence of Glacial acetic acid to obtain the corresponding 1,3,5-trisubstituted pyrazolines. The synthesised Heterocyclics were characterised on the basis of physical, chemical tests and sectroscopical data. These compounds were tested for acute anti-inflammatory activity and anti-oxidant activity using Carragenan induced rat paw oedema method and DPPH (diphenyl picryl hydrazyl) radical scavenging

methods respectively. Evaluation of the compounds revealed remarkable anti-inflammatory activity reflected by their ability to reduce the Carragenan induced inflammation in rats and also appreciable anti-oxidant activity.

BP 22 Design, synthesis of pharmacological evaluation of 9-amino substituted acridine derivatives as antimitotic and cytotoxic agents

Gayatri Das*, D.H. Krishna, D.R. Krishna, and A.R. Rao

*Medicinal Chemistry Research Division, University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, AP, India.

Acridine derivatives were found to have analgesic and antiinflammatory mydriatic, antibacterial, antiprotozoal, antimalarial, antihistaminic, antitrypanosomal activities. They also have anticancer activity which was found to be because of the ability of acridine pharmacophare to intercalate DNA & inhibit topoisomerase enzymes.

9-Amino substituted acridines were prepared by using 9-chloroacridines as intermediates which were treated with different primary amines, phenyl thiourea and N,N-dimethyl-5-aminouracil to give N-phenyl N'-(9-acridinyl)thioureas and 6-[N-(9'-acridinyl)amino]-1,3-dimethyl pyrimidin-2,4-(1H, 3H)diones respectively. S-methyl-(acridin-9-yl)dithiocarbonate were synthesized by treating 9-Amino acridine with (CS_2) carbondisulphide, (DMS) dimethylsulphate in (DMSO) dimethyl sulphoxide. The structures were all confirmed by spectroscopic method. Compound V & II showed significant antimitotic activity. Compound I possesses cytotoxic activity with an IC 50 value of 90 mM and compound II showed a maximum of 40% inhibition at and above 10 m M concentration on A-549 cell line by MTT assay.

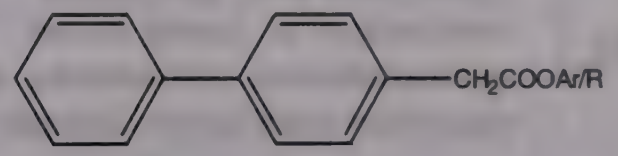
BP 23 Design and synthesis of mutual prodrugs of 4-BPA and phytophenolics

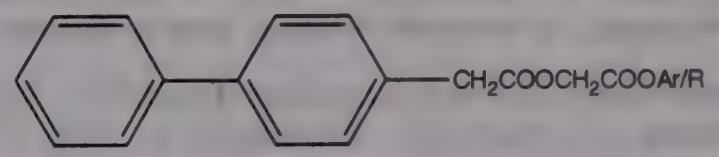
Pritam Dev Sharma, Senthilkumar Chandiran* & Sumeet Kansal

University Institute of Pharmaceutical Sciences, Punjab University, Chandigarh-160 014.

The gastrointestinal toxicity of the acidic nonsteroidal antiinflammatory drugs (NSAIDs) is one of the most challenging problems in medicinal chemistry. The direct contact mechanism appears to play the major role in the production of the gastrointestinal lesions. Recent studies have revealed that local generation of various reactive oxygen species (ROS) may be playing a significant role in the formation of gastric mucosal lesions associated with NSAIDs therapy. These results indicate that coadministration of NSAIDs and antioxidants may reduce the risk of gastrointestinal ulcerogenic side effects. However, there are potential advantages in giving such different drugs with complementary activities in the form of single chemical entity. Such agents are named as mutual prodrugs that are designed with improved physiochemical properties and release the parent drugs at the site of action.

We have designed and synthesised mutual prodrugs of topically used NSAID 4-biphenylacetic acid (4-BPA) and antioxidant phytophenolic/alcoholic compounds. For this purpose, 4-BPA has been conjugated with different phytophenolic/alcoholic compounds by esterification, directly as well as through spacer. The phytoconstituents used include thymol, guaiacol, eugenol as well as menthol, which have been traditionally in use for their flavoring properties and have well documented safety profiles. Structures of the synthesised compounds have been confirmed by spectral (IR,NMR,MASS and Elemental analysis)studies.





Ar/R- thymol, guaiacol, eugenol and menthol

BP 24 Synthesis and study of some new 1-substituted imidazoles

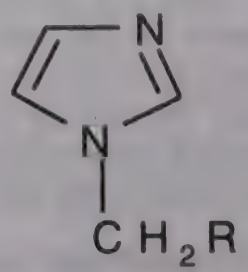
S. Ganguly[1]* and B. K. Razdan[2]

1. Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi -835215, Jharkhand
2. S. Bhagwan Singh PG Institute of Biomedical Sciences, Balawala, Dehradun –248161.

Imidazole nucleus in its various oxidation states has proved to be a very good source of medicinal agents. The various activities associated with this moiety include antiprotozoal, antifungal, H_2-antagonist, α-adrenergic agonist and blocking, antihistaminic and other activities. In the present paper we wish to report a series of novel 1-substituted imidazoles (I), which have been synthesized from the intermediate 1-chloromethylimidazole.

1-chloromethylimidazole was synthesized by condensing the sodium derivative of imidazole with methylene chloride. Various 1-aminomethylimidazoles (I) were synthesized by condensing the appropriate

amine with 1-chloromethylimidazole by refluxing in propanol. All the compounds were characterized by their spectral data and elemental analyses.



R = 1° & 2° aliphatic and aromatic amine

All the compounds were subjected to a gross behavioral battery of tests. Compound 1-isopropylaminomethylimidazole at a dose level of 100mg/kg affected several measures of behavioral test battery indicating its broad neurological activity. The observations suggest that the brain is an important target for its action.

BP 25 Synthesis and biological evaluation of some novel quinazolinone derivatives as possible anticancer agents

Saurabh K. Banerjee*, N.P. Padamavathy, V. Murugan, K. Sumanth Prabhu, and B. Suresh

Department of Pharmaceutical Chemistry, J.S.S College of Pharmacy, Ootacamund- 643 001, Tamilnadu.

Quinazolinones have been reported for their diveresed biological activities like antiviral, antimicrobial and anticancer. Similarly compounds containing b-diketones have been found to be potent antioxidant, antiangiogenic and anticancer agents. In view of these findings it has been thought worthwhile to synthesize 4-chloro-1-[4-(6,8- disubstituted-2-chloromethyl-quinazolin-4one-3-yl)-phenyl] butane1,3-dione derivatives as novel series of quinazolinonyl b-diketones bearing bromine at 6 and 6,8 chlorine at 6,8 and iodine at 6th position of quinazolinone moieties respectively (III $_{A-E}$).

The title compound (III $_{A-E}$) derivatives were synthesized by the reaction of corresponding 2-chloromethyl-3-(acetophenone-4-yl)-4-(3H) quinazolinone (II$_{A-E}$) with ethylchloroacetate in presence of sodium methoxide in dry methanol and using diisopropyl ether as solvent. Compound(IV) 2-(N-morpholinomethyl)-3-(acetophenone4-yl)-4-(3H) quinazolinone was prepared by the reaction of (II$_A$) and morpholinone in the presence of potassium Carbonate and dry methanol. The compound (IV) was synthesized without b-diketones to compare the effect of b-diketone incorporation. The intermediates N-chloroacetyl anthranilic acid derivatives (1$_A$-$_E$) and 2-chloromethyl-3-(acetophenon-4-yl)-4-(3H) quinazolinone (II$_A$-$_E$) were prepared by standard procedures. The structures of various compounds synthesized were assigned on the basis of spectral analysis. The compounds were screened for *in vitro* antitumour activity, cytostatic activity, angiogenesis inhibition studies and antioxidant studies.

Some of the compounds showed significant activities. Our study concluded that * b-diketone group at position 3. * Halogen group at position 6 and/or 8.* and free chloromethyl group at position 2 were essential for antiangiogenic and antioxidant activity.

BP 26 Synthesis and biological evaluation of new isatin hydrazone derivatives

P.V.R. Chowdary* and Tarun Goel.

Dept. of Pharmaceutical Chemistry, College of Pharmaceutical Sciences, MAHE, Manipal - 576 119

Isatin derivatives possess anti-inflammatory, anti microbial and various pharmacological activities.Benzimidazoles, Norflaxacin and Quinazolinones are known for their antimicrobial properties. Similarly INH is a known anti-tubercular agent. Keeping in view of the pharmacological and antimicrobial importance of these different molecular moities, it is our endeavour to combine these moities with Isatin by appropriate synthetic routes and screen for their anti-tubercular, anti-bacterial, antfungal, antiinflammatory and anti-oxidant activities. Isatin was condensed with the hydrazides of Benzimidazole, Nicotinic acid, Isonicotinic acid, Norflaxacin, Indophenazine, Quinazolinone and Paracetamol. The structures of these compounds were established by their physical and spectral data. The synthesised compounds were screened for the above biological activities. All the compounds showed anti-tubercular activity at 100mg/ml and two at 50mg/ml. One compound showed inhibitory action on both Gram +ve and Gram -ve bacteria. Two compounds showed significant oedema inhibition and anti-oxidant activity.

BP 27 HyperChem release 6.0, a novel approach for the design of *H-pylori* inhibitors

Anwar R. Shaikh*, Velingkar V.S., Kamble S.B. and Chandrababu

* K.M. Kundnani College of Pharmacy, 47, Dr. R.G. Thadani Marg, Worli Sea Face, Mumbai 400 018

1. Swami Prakash Anand Ayurvedic Research Centre (SPARC) Juhu, Mumbai 490 066

The explosive development of computer technology and of methodology to calculate molecular properties have increasingly made it possible to use computer techiques to aid the drug development process with the aim of making it more rational. The so

called *rational drug design* methods employ computational chemistry in an attempt to develop new ligands, which are able to bind to the target enzymes or receptor. The use of computer techniques in this context is often called *Computer Aided Drug Design* (CADD). In the absence of an experimentally determined 3D-structure for the receptor, rational ligand design may be performed by the use of an indirect strategy based on the analysis and comparison of molecular properties and receptor binding data for known receptor ligands.

The aim of this presentation is to explain how some of the software tools (HyperChemRelease 6.0) help in designing some novel organometallic compounds, which were found to be specifically active against *Helicobacter pylori*, a prevalent human pathogen responsible for more than 90% of the cases for ulcer.

The present study involved,

QSAR properties like atomic partial charges, vanderwaals and solvent accessible surface area, vanderwaal's surface bounded molecular volume, mass, log p, molar refractivity, polarizability were computed for the above mentioned compounds through Hyperchem release 6.0 (Hypercube Incl.) Atom wise contribution for the QSAR properties was done in search of role of each and every atom for the change in physicochemical parameters. Model build studies were performed in search of most stable confirmation of the synthesized compund. Bond length comparison was done as a basis for drug receptor studies in details.

The above mentioned complexes were prepared by reacting a bismuth salt with the selected drug under specified conditions. They were characterized by various spectral techniques. The drugs were selected from various categories of antibiotics.

These calculations are empirical which suggest that hydration energy in the range of -22.0 to -28.0 Kcal/mol, log P, 1.004 - 02.07, Refractivity 86-214A^3 and Polarizablity, 46-89 A^3 are the minimum requirements for exhibiting anti *H.pylori* activity. Model build studies suggest that the observed RMS gradient values (less than zero in all compounds) suggest that the compounds have achieved energy minima as well as the most stable confirmation.

From the experimental work performed, following conclusions were drawn;

1. The compounds predicted were found to be specifically active against *H. pylori.*
2. The parameters computed for the synthesized compounds were found to exhibit optimum anti ***H. pylori*** activity.
3. Such type of compounds can therefore specifically be directed for the treatment of ulcers caused by ***H.pylori.***
4. HyperChem Release 6.0 thus found to play a major role in the development of some new generation anti ulcer agents.

BP$_{28}$ Synthesis and antiplatelet activity of some new 3-Phenyl-4(1H) quinolones

Neelima S.J.*, Asmita G. and Achaiah G.

University College of Pharmaceutical Sciences, Kakatiya University, Warangal 506 009

Literature survey reveals that 4(1H) - quinolones with aryl substitutents on the ring have been associated with varied biological activities.

Simple 2-phenyl and 3-phenyl-4(1H)-quinolones which are isosteres of flavone and isoflavone respectively have showed potent inhibitory effect on platelet aggregation induced by arachidonic acid with IC_{50} values 9.63 and 0.17 μM). It has also been found later that 5,7-dimethyl substitution on 2-phenyl-4(1H)-quinolone resulted in increased activity, 5-ethyl-2-phenyl-4-quinolone displayed the highest potency.

In view of the greater potency of 2-phenyl & 3-phenyl-4(1H)-quinolones a series of title compounds with varied substitution viz: methyl, methoxy, chloro, nitro have been synthesized through appropriate synthetic routes using ethylphenyl acetate (1) and ethyl formate (2) as starting materials. 1&2 react in the presence of sodium hydride to give α-formyl derivative of 1, which on condensation with various substituted anilines and subsequent cyclisation with polyphosphoric acid resulted in 3-phenyl 4(1H)-quinolones (5). The compounds have been purified by recrystalisation / column chromatography characterized by their spectral properties (IR/NMR).

Final compounds have been screened for the anti-platelet activity using modified Born method and simple 3-phenly-4(1H)-quinolone showed IC_{50} value of 0.13μM whereas aspirin used as standard showed IC50 value of 20.8μM. Chloro substitution at position 6 did not alter much of the activity. But methyl and methoxy substitution at position-6 resulted in loss of activity.

BP$_{29}$ Development of some anti-inflammatory prodrugs

U. J. Joshi, Bharat Lakhawat*, Rajkumar Dubey, S. S. Borude, p.p.Gate

Department of Pharmaceutical Chemistry, Principle K. M. Kundanani College of Pharmacy, 47, R. G. Thadani marg, Worli, Mumbai-400018.

Nabumetone is a non acidic NSAID which metabolises by microsomal oxidation in liver to give 6-methoxynaphthalene acetic acid (6-MNA). It is this

metabolite which possess anti-inflammatory activity. The bioavailibility of 6-MNA, however is only 35%.

6-MNA itself can be converted to a wide range of compounds. Esterification, particularly will give prodrugs with different half lives and release patterns. These may help to deliver active molecules at a continous rates at the desired site, depending upon rate of hydrolysis. The work involves the synthesis and study of rate of hydrolysis of prodrugs.

Prodrugs of 6-MNA were prepared as follow:

1. synthesis of 6-MNA from b-naphthol via 2-methoxynaphthalene and 2-acetyl-6 methoxynaphthalene.
2. esters of 6-MNA were prepared by using various alcohol and alkoxy carbonyl alkyl esters using esters.
3. study of rate of hydrolysis the esters derivative of 6-methoxy-2-naphthalene acetic acid using buffer solution and plasma respectively.

Various simple esters and alkoxycarbonyl alkyl esters have been prepared. When the hydrolysis pattern of these esters were studied, the compounds showed variable rates of hydrolysis.

The ester prepared from simple alcohol showed befter release pattern than the alkoxy carbonyl alkyl esters.

Hydrolysis of alkoxy carbonyl alkyl esters after 4 hour-

	A	B	C	D	E
Chemical hydrolysis	89.29%	95.29%	86.77%	0%	0%
Enzymatic hydrolysis	33.63%	0%	22.04%	0%	0%
Hydrolysis of simple esters after 4 hour					
	F	G	H	I	J
Chemical hydrolysis	-	97.20%	95.63%	13.86%	-
Enzymatic hydrolysis	-	99.20%	58.70%	66.25%	99.97%

BP 30 Antimalarial activity of sulfones

Swati G. Dharap* and S. S. Mahajan

C. U. Shah College of Pharmacy, S.N.D.T. University, Mumbai-49.

Malaria is one of the major infectious diseases in the world today, despite years of efforts, first to eradicate it and subsequently to reduce its impact on mortality and morbidity. *Plasmodium falciparum* is the most virulent form of the four human plasmodium species, causing malaria. It is potentially life threatening, increasing in prevalence and becoming even more resistant to in-use drugs. Immunoprophylaxis holds promise but effective vaccine is still not available.

The emergence of multidrug-resistant strains of plasmodia has created a near desperate situation and hence there is an urgent need for the development of structurally novel and effective antimalarials.

The experimental part involved synthesis and antimalarial testing of ten sulfones. The synthesis of ten sulfones was carried out by conventional methods, using chlorosulfonic acid. The percent yield of sulfones was calculated. The purity of the compounds was checked by melting point and thin layer chromatography. All the compounds were characterized by IR and NMR spectroscopy.

The antimalarial testing of ten sulfones was carried out by Rane's test using albino mice. Three to four week old male mice, weighing 18-20 gms each, were infected by *Plasmodium berghei,* intraperitoneally. The compounds were suspended in distilled water by the addition of few drops of tween 80. A single dose was administered subcutaneously, 72 hours after the infection. The mortality was observed and mean survival time was calculated.

- Most of the sulfones were obtained in good yield.
- Four sulfones showed good antimalarial activity, *in vivo.*
- One sulfone showed moderate antimalarial activity, *in vivo.*
- Sulfones were synthesized using conventional methods.

Good antimalarial activity was observed *in vivo, in albino* mice using very simple molecules from the class of sulfones.

BP 31 Synthesis of some new tricyclic thieno-(2,3-d)-1,2,3-triazin-4-ones as potential antimicrobial agents

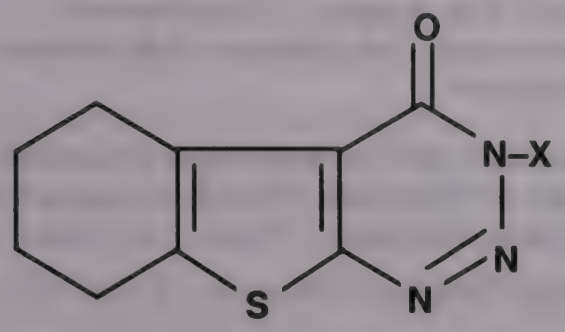
J. Saravanan*, S. Mohan[1]

*M.S. Ramaiah College of Pharmacy, M.S.R.I.T. Post, Bangalore 560 054.

1. PES College of Pharmacy, Hanumanthanagar, Bangalore 560 050

A number of thiophenes such as substituted thiophenes, condenced thiophenes & few 1,2,3-triazines have been reported to posses antibacterial & antifungal activity. These observations led to the design and development of some new 1,2,3-triazin-4-ones with thiophene in one framework with the presumption that the new thienotriazines could produce new compounds of better antimicrobial activity, we have synthesised ten different 2-amino3-N-substituted carboxamido-4-5-pentamethylene thiophenes (Ia-j) by adapting a well known and versatile Gewald reaction. Later the compounds I a-j containing an amino group bearing

aryl carboxamides at ortho position were subjected to cyclization by diazotization with sodium nitrite in hydrochloric acid at ice cold condition to yield the corresponding title compounds (IIa-j). The ten new compounds were characterized by spectral data and were subjected to antimicrobial screening against four bacteria and three fungi by agar plate diffusion method using ampicillin & miconozole as standards. All the compounds exhibited anti microbial activity. Of which the compound IIi with p-chlorophenyl substituent at X exhibited significant anti microbial activity comparable to standards.



{ II a - II }

BP 32 Anti-inflammatory activity of 5-Thiazolyl-oxo acetic acid derivatives

Parendu D. Rathod., Ajay D. Pillai., Franklin. P. X*., Kamala K.Vasu., Harish Padh., V. Sudarsanam

B.V. Patel Pharmaceutical Education & Research Development (PERD) Centre, Thaltej, Ahmedabad 380 054

Romazarit (Roche, Ro-31-3948) a molecule which showed good anti-rheumatic activity in various models, was abandoned in the phase II clinical trial due the formation of bladder tumors in rodents on chronic administration. Taking Romazarit as a lead molecule, a number of thiazoles were designed by incorporating drug like features in the side chain at 5th position of the 5-memebered heterocycle. Initial synthesis of 5-thiazolyl-oxo-oximino/methoximino propionic acid derivatives showed good anti-inflammatory activity. In order to study the effect of acetic acid type functionality in the side chain and also to evaluate the change in activity profile of these compounds by shortening the distance of ester functionality from the thiazole, the synthesis of compounds 5-thiazolyl -oxo-acetic acid was under taken.

5-thiazolyl-oxoacetic acid ethyl ester derivatives were prepared. All compounds were characterized by appropriate spectral and analytical methods. These compounds were screened for their anti-inflammatory activity in Carageenan induced paw edema model. The compounds of this series showed moderate activity. The molecule with an amino group at the 4th position (P-43) is the only compound which showed good activity. It appears that an optimum lipophlic group and NH group at 2nd position may be necessary for activity

BP 33 Synthesis, characterization, analgesic and anti-inflammatory activity of carboxamides of aminothiazolyl chlorocoumarin

Anuradha D[1], Jayashree B.S.[2]* and Venugopala K.N.[2]

1. Department of Pharmaceutical Chemistry, Kamala Nehru Polytechnic for Women and Sarojini Naidu Pharmacy Maha Vidyalaya, Hyderabad.
2. Department of Pharmaceutical Chemistry, Al - Ameen College of Pharmacy, Hosur Road, Near Lalbagh Main Gate, Bangalore-560 027, Karnataka.

Coumarins have been reported for their diversed biological activities like anticoagulant, HIV protease inhibition, antibacterial, analgesic and anti-inflammatory activities. Thiazoles have also been reported for their anti-inflammatory activity.

Attempts have been made to synthesize and characterize different carboxamides of 2'-amino-4'-(6-chloro-3-coumarinyl) thiazole for exploiting their analgesic and anti-inflammatory activity. The parent compound, 2'-amino-4'-(6-chloro-3-coumarinyl) thiazole was prepared by the cyclization of the synthesized 3-bromoacetyl-6-chlorocoumarin intermediate with thiourea in ethanol medium. The parent amine was treated with different acid chlorides to obtain carboxamides of 2'-amino-4'-(6-chloro-3-coumarinyl) thiazole. The purified compounds were characterized by IR, ^{1}H-NMR, and Mass spectral studies. Compounds synthesized were screened for their analgesic activity by acetic acid induced writhing method at a dose of 100mg/kg body weight for standard and test samples using aspirin as standard. The anti-inflammatory activity by carrageenan induced rat hind paw oedema method at a dose of 10.6mg/ 200g body weight for standard Ibuprofen and test samples. The activities of the test compounds were compared with control.

Out of the eight carboxamides screened for their anti-inflammatory activity, two of them namely 2'-(4''-chlorobenzamido)-4'-(6-chloro-3-coumarinyl) thiazole, and 2'-(2''-chlorobenz amido)-4'-(6-chloro-3-coumarinyl) thiazole and parent amine 2-amino-4'-(6-chloro-3-coumarinyl) thiazole showed activity at 66.66, 43.01 and 46.23% respectively with respect to standard ibuprofen activity at 89.24%. However, when the test compounds were evaluated for their analgesic activity compounds such as 2'-(benzamido)-4'-(6-chloro-3-coumarinyl) thiazole, 2'-(2''-nitrobenzamido)-4'-(6-chloro-3-coumarinyl) thiazole, 2'-(4''-nitrobenzamido)-4'-(6-chloro-3-coumarinyl) thiazole and 2'-(4''-

chlorobenzamido)-4'-(6-chloro-3-coumarinyl) thiazole showed better activity at 46.50, 43.70, 43.70 and 40.80% respectively when compared to compounds such as 2'-(2''-chlorobenzamido)-4'-(6-chloro-3-coumarinyl) thiazole, 2'-(3''-bromobenzamido)-4'-(6-chloro-3-coumarinyl)thiazole at 36.80, 35.80 and 35.80% respectively. However, parent amine 2-amino-4'-(6-chloro-3-coumarinyl) thiazole showed activity at 40.30% whereas the standard Aspirin showed activity at 31.03%.

From our study it is speculated that some of the carboxamides of substituted thiazolyl coumarin could become potential candidates for their analgesic and antiinflammatory activity.

BP$_{34}$ Evaluation of newly synthesized cinnoline fused pyrido benzopyran–2–ones as potent antitubercular agents by microplate alamar blue assay method (MABA)

P. Ramalingam*, T. K. Ravi, S. Krishnan

Both benzopyran–2–ones and cinnoline were reported to be associated with a wide spectrum of antibacterial, antifungal and antimycobacterial activity. A number of ring-fused systems are known to exhibit increased and potent biological activity. In view of obtaining more potent anti tubercular agent, our work has been directed to synthesize new pentacyclic fused ring system which posses both benzopyranopyridine and cinnoline moiety. There were totally nine compounds synthesized and all the compounds were screened for *in vitro* antimycobacterial activity against *Mycobacterium tuberculosis* H_{37} *Rv* by microplate alamar blue assay.

4–Chlorocoumarin and 4–amino–3–carboxy cinnoline were subjected to Ulmann Reaction to give 4–[(3-carboxy 3,4 dihydrocinnoline) amino] benzpyran-2-ones (Compd 3), which on cyclization with poly phosphoric acid and phosphoryl oxy chloride afforded compound 4 {2-oxo-1-benzo pryano (3,4b)-4-oxo trihydropyride (6,5c) cinnoline} and compound 5 {2-oxo-1-benzopyrano (4,3b)-4-chlorodihydropyrido (6,5c) cinnoline} respectively. The compound 5 was subjected to synthesize compound $6_{(a\text{-}e)}$ and 6_f by condensing with para substituted aniline and morpholine respectively. All the compounds were recrystallized from ethanol and the structure was determined by spectral data. The purity of the compound was determined by performing thin layer chromatography. The synthesized compounds were evaluated for their antimycobacterial activity against *Mycobacterium tuberculosis* $H_{37}Rv$ by microplate alamar blue assay method.

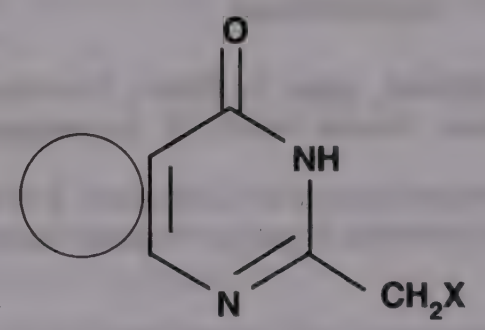
All newly synthesized compounds were found to be effective at a concentration of 0.05μgm/ml. But at a concentration of 0.01μgm/ml (a concentration less than the MIC of Isoniazid) the morpholine derivatives (6_f) was found to be more potent than the reference compound isoniazid. The remaining compounds synthesized in the series were found to be equipotent to isoniazid.

BP$_{35}$ Synthesis, antihyperlipeamic activity & QSAR of some 2-substitutedmethylpyrimidin-4(3H)-ones

K.S. Jain[1]*, S.S. Kadam[1], GirishKumarK[1], M.K. Kathiravan[2], P.B. Miniyar[2], S.M. Meher[2] & C.J. Shishoo[3],

1. Department of Pharmaceutical Chemistry, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune – 411 038.
2. Sinhgad College of Pharmacy, Pune –411 041
3. L.M.College of Pharmacy, Ahmedabad-380 009.

Synthesis, antihyperlipaemic evaluation and QSAR of some condensed & mononuclear 2-substituted-methylpyrimidin-4(3H)-ones has been undertaken. This work has been a logical extension of



the efforts towards lead optimization for this type of pyrimidine derivatives, for improved anti-cholesterol activity.

While, the basic 2-substituted-methylpyrimidin-4(3H)-one skeleton has been retained, changes have been effected with respect to the other ring (A), fused to the pyrimidine ring. These changes range from a wide variety of aromatic (Benzene) to heteroaromatic (Thiophene,, pyrazole, triazole, pyrimidine, quinazoline) rings to no ring fusion at all (mononuclear).

Compound, 1d, has exhibited activity comparable to earlier lead and drugs like clofibrate and gemfibrozil. when the antihyperlipaemic activity was evaluated in *Wistar* albino rats using enzymatic kits to analyse serum cholesterol levels.

Preliminary QSAR involving multiple regression analysis of the results (observed biological activity) with the variables (physicochemical properties of the compounds), reveals better influence of lipophilic parameters.

BP 36 Synthesis and Evaluation of some Benzofuran compounds as Hypoglycemic agents

M.B. Raju., Dr. S.M. Shantakumar, K. Raghavendra, T.Pramila, A. Vinodkumar. *

V.L.College of Pharmacy, Raichur 584 103, Karnataka

In the present work twelve Benzofuran derivatives of Sulfonoyl Urea were synthesized and screened for Hypoglycemic activity.

The key intermediate benzofuran-2-Carboxy hydrazide was prepared from Salicylaldehydes. The hydrazine was reacted with 4 acetamid benzenesulfonylchloide to get â-(p-acetamido benzosulfamino) –2- (carbamino) benzofurans (I)a-l. These were hydrolysed with Conc Hcl to get the corresponding â-[(p-aminobenzosulfamino)]-2-(carbamino) substituted benzofurans (II a-l).Appropriate arylisocyanate/arylisothiocyanate were reacted with (II a-c) dioxan to get the title compound (IIIa-l)

The structure of the compounds synthesized were assigned on the basis of elemental analysis IR, ^{1}H-NMR and Mass Spectral data. The compounds were screened *in vivo* for hypoglycemic activity in albino rats by standard methods, compounds IIIa, IIId, IIIf, and IIIi displayed significant hypoglycemic activity.

BP 37 Design, synthesis, biological screening, toxicity evaluation and ADME prediction of novel squalene epoxidase inhibitors as antifungal agents

Vishal V. Kulkarni, *Prashant S. Kharkar and Vithal M. Kulkarni

Institute of Chemical Technology, University of Mumbai Matunga (East), Mumbai 400 019

Incidences of fungal infections have increased dramatically in the last few decades. The increased intensity of life-threatening fungal infections and the development of resistance to the currently used antifungals warrant the search for novel, alternative therapies. Biosynthesis of ergosterol and other membrane sterols is an important pathway in fungi. Squalene epoxidase (SE) enzyme present in fungi catalyzes a major step in ergosterol biosynthesis. The enzyme is a target of action for allylamine antifungals such as naftifine, terbinafine, etc. Based on the previous 3D QSAR studies, we have designed and synthesized a novel series of fungal SE as antifungal agents. The synthesized compounds were screened for antifungal activity in vitro using *Candida albicans ATCC 24433*. Most of the compounds have shown promising antifungal activity. Few compounds were evaluated for acute oral toxicity using animal model. These NCEs were found to possess safer toxicity profile. The pharmacokinetics of these NCEs was predicted using software. One of the compounds exhibited pharmacokinetic profile similar to standard drug terbinafine. These compounds are likely to enter into the next stages of drug discovery cycle.

BP 38 Three dimensional quantitative structure activity relationship studies of PDK inhibitors

Teshome Leta*, M. E. Sobhia, P. Senthil Kumar and P. V. Bharatam

Department of Medicinal Chemistry, National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, S. A. S. Nagar (Mohali) – 160 062, India.

Mitochondrial pyruvate dehydrogenase complex (PDC) is a large, multienzyme complex composed of multiple copies of its four components: E1, E2, E3, and E3-binding protein. PDC catalyzes the irreversible conversion of pyruvate to acetyl-CoA, which then proceeds to oxidation through the tricarboxylic acid cycle or conversion to fatty acids for storage. The flux through this complex is controlled by the phosphorylation state of three serine residues on the E1a subunit of pyruvate dehydrogenase (E1). When glucose and insulin levels are high, the serine residues are dephosphorylated by an active pyruvate dehydrogenase phosphatase, which results in an active complex and the flow of energy from glycolysis to oxidation or storage. In fasting or diabetes, the pyruvate dehydrogenase kinase (PDK) associated with the complex is activated and also induced, resulting in phosphorylation and inactivation of the E1 enzyme. This serves to preserve the three-carbon skeleton of the pyruvate for gluconeogenesis, which maintains serum glucose levels during fasting but also contributes to pathologic hyperglycemia in diabetes. Hence, activation of PDC complex through inhibition of PDK can alleviate the associated pathological hyperglycemia in diabetes.

A 3D-QSAR CoMFA analysis was carried out to find out the structural requirement of PDK inhibitors. CoMFA model was derived from a training set composed of 45 diverse set of (R)-3,3,3-Trifluoro-2-hydroxy-2-methylpropionic acid derivatives of PDK inhibitor molecules. Eleven compounds, which were not included in model derivation, were used to validate CoMFA model. All compounds were superimposed to the template structure (14E) by database alignment strategies in SYBYL. CoMFA yielded the predictive model, with r^2 values of 0.562 (cross-validated) and 0.990 (conventional). The model exhibited robust external predictivity, r^2pred of 0.875. The details of this CoMFA model along with molecular docking studies will be presented in this poster.

BP 39 Structural requirements for 1,2-diarylimidazole as COX-II Inhibitors - a hansch analysis

Sudha Vengurlekar*, K.P. Sarathy, R. Giridhar and M.R.Yadav

Pharmacy Department, Faculty of Technology & Engg., Kalabhavan, M.S.University Baroda.

Inflammation is a response of vascularized living tissue to local injury or infection and is characterized by redness, swelling,pain,fever,etc. Nonsteroidal anti-inflammatory (NSAIDS) are widely used agents for the treatment of inflammation. The chronic usages of such drugs has been linked to the induction of GIT lesions,perforations and bleeding. These side effects are related to the inhibition of COX-I enzyme present in GIT.

A Series of 1,2-Diarylimidazole has been found to contain selective inhibitory action of the human COX-II enzyme. In this communication an attempt has been made to identify the structural requirements for COX-II and COX-I enzyme inhibition in 1,2-Diarylimidazole system. In this series the reported biological activity was taken as log(1/IC50)M, which is used for the stepwise regression analysis. Different physicochemical parameters [p , s / s ,s , MR , V, SA] were taken for each substituent. Multiple regression analysis was performed using QSAR software developed in this department. ALCHEMY 2000 was used for calculation of certain other molecular parameter. The stepwise regression analysis generated a large number of QSAR equation, out of which the best equation was found to be as given below-

$$\text{Log}(1/IC_{50}) = 0.9201\delta(a_3+a_4+a_5) - 0.1327Va_5 - 0.0745(s(a3) + s(a5)) - 6.2540\, s(b4) + 11.3426$$

where : a3,a4,a5 are the substitution at 3 , 4 and 5 position of the ring A.

$n = 65,\ r = 0.8583,\ s = 0.4886,\ F = 33.0214$

From the result obtained it was concluded that lipophilic parameters with smaller surface area in ring A at 3 , 4 and 5 positions and electron withdrawing groups at 3 and 5 position in ring A , and 4 position in ring B are highly favourable for COX-II inhibitory activity in this series of imidazole compounds.

BP 40 Synthesis and evaluation of certain ketorolac analogs with an improved therapeutic profile

P.K. Halen*, K.K. Chagti, R. Giridhar & M.R. Yadav

Pharmacy Department, Faculty of Technology & Engineering, Kalabhavan, M.S. University of Baroda, Vadodara

Besides their desirable pharmacological action most of the NSAIDs also possess the side effect of inducing gastric ulceration and bleeding. The gastrointestinal damage is generally attributed to two factors one of which is the local GI irritation due to the free carboxyl acid moiety which is common to most of the acidic NSAIDs. The local inhibiton of prostaglandin synthesis and back diffusion of hydrogen ions contribute to the local effect. To prevent this topical effect, blocking of the carboxyl group temporarily has been done in the past involving the synthesis of esters and amides which release the parent drug after cleavage in the plasma. With the aim of abolishing the GI toxicity due to the free carboxyl group the present work was undertaken involving the synthesis of some N,N-disubstituted b-aminoethyl esters of the NSAID ketorolac which, also satisfied the structural requirement for them to exhibit anticholinergic activity. The anticholinergic activity was incorporated with the expected advantage of further decreasing the GI toxicity by decreasing the gastric acid secretion. All the synthesized derivatives were characterized by their physical and spectral data. All the compounds were found to be stable in pH 2.0 and 7.4 buffers and exhibited enzyme catalysed hydrolysis in 80% human plasma. Further all showed anticholinergic activity when evaluated on isolated rat ileum. Similar antiinflammatory activity was possessed by these derivatives and the parent compound at equimolar concentrations. Moreover, all the derivatives were found to be much less ulcerogenic than the parent drug at equimolar dosage.

BP 41 16ξ-dimethylamino-3-pyrrolidino-5-androstene dimethiodide as a potential neuromuscular blocking agent

Sitesh R Patel, M. M. Ganesh, R. Ramajayam*, R. Giridhar and M.R. Yadav

Pharmacy Dept., Faculty of Tech. & Engg., Kalabhavan, M.S. University of Baroda, Vadodara 390 001

Androstenolone (1) acetate was nitrosated with amyl nitrite in alkaline conditions to offer the 17-keto-16-oximino derivative (2). 17-keto function in compound (2) was reduced to methylene function by Huang-Minlon reduction to afford the oxime (3). Sodium-*n*-pentanol reduction of the oxime(3) followed by N-methylation using formaldehyde-sodium borophydride afforded a mixture of two isomeric 16-dimethylamino derivatives. Isolation of the lower sport (4) was achieved by column chromatography using silica gel as adsorbent. Oppenauer oxidation of the 3-hydroxyl derivative (4) using alumnium isopropoxide-cyclohexanone-toluene system yielded the 3-keto 4-en (5) which on pyrrolidine treatment gave the enamine (6). The enamine (6) was reduced using sodium borohydride to the 16ξ-dimethylamino-3β-pyrrolidino-5-androstene (7). The bistertiary amine (7) was quaternised to the

dimethiodide (8) using methyl iodide. The bisquaternary ammonium compound was (8) biologically evaluated as neuromuscular blocking agent on sciatic nerve muscle preparation in rat using candocuronium and pancuronium as standard drugs. The compound (8) was found to be less active than both the standard drugs.

BP 42 P-amidophenol and acetylated phenol derivatives of certain commonly available NSAIDS as more cox-II selective inhibitors

Datta M Nimekar, Pathik S Brahmkshatriya*, R. Giridhar and M.R. Yadav

Pharmacy Deptt, Faculty of Tech. & Engg., Kalabhavan, M.S. University of Baroda, Vadodara-390001

Commonly used NSAIDs have serious GI side effects on long term use due to their nonselectivity towards COX enzymes. One of the approaches adopted to reduce this toxicity is to convert them into nonacidic compounds. This approach could reduce not only their GI toxicity but could be helpful to increase the selectivity towards COX-II. Developing a new drug molecule is a costly and time consuming affair, hence, it is logical to improve upon the existing drugs. The objective of the present work is to mask the acidic group by synthesizing p-amidophenol and acetylated phenol derivatives of certain commonly available NSAIDs. The synthesized compounds have the structural similarity to paracetamol; hence, they are expected to exert paracetamol like activity also. All the synthesized derivatives were characterized by the spectral data. These derivatives were evaluated for their ulcerogenic potential and anti-inflammatory activity. Screening of antipyretic and analgesic activities is in progress. The work pertaining to their synthesis and activity profile of the synthesized compounds would be presented.

BP 43 A fujita-ban modified de novo study on triazolinone based balanced AT_1 - AT_2 receptor antagonists

Dharmendra L.Patel*, R.Giridhar and M. R. Yadav

Pharmacy Department, Faculty of Technology and Engineering, Kalabhavan, M.S.University of Baroda, Vadodara. 390 001

Two distinct types of Angiotensin-II receptors have been identified namely, AT_1 & AT_2. AT_1 receptor has been established to mediate the known physiological effects of AT_1 including regulation of blood pressure. AT_2 receptor have been linked to phosphotyrosine phosphatase activity. The plasma concentration of A II increases considerably in presence of AT_1 selective antagonists although the physiological effect of prolonged stimulation of AT_2 receptor by increased level of A II is not known. Nevertheless, simultaneous inhibition of both the type of receptors might be beneficial.

N^2 -Aryl triazolinone biphenyl sulphonamides have been reported to possess both AT_1 & AT_2 antagonistic activities in the literature. It was thought to identify the groups responsible for binding to both the receptors by performing a Fujita-Ban modified de novo study to this series of compounds. The software 'QSAR' developed in this department was used for this purpose. As much better correlation was obtained for AT_2 than for AT_1. Fluorine at 3- position in the biphenyl system contributed significantly positively for AT_2 binding while n-propyl group at C-3 position in the other phenyl ring of the biphenyl system contributed negatively for AT_1 receptors. For rest of the other groups, there was not of much difference in their contribution to binding for either AT_1 or AT_2 receptors.

BP 44 Pharmacological activity of some ruthenium complexes bearing fluoroquinolones and coumarins

Subhas S. Karki,* U K Mazumder[1], Malaya Gupta[1], S Bhattacharya[1], T Sivakumar[1].

* K.L.E. Society's College of Pharmacy, Bangalore – 560 010.

1 Pharma. Tech. Dept., Jadavpur University, Jadavpur, Kolkata-700 032.

The coordination of the ligands (3-amino coumarin, 3-hydroxy coumarin and fluoroquinolones) to both cis-$[Ru(bpy)_2]Cl_2$ and cis-$[Ru(phen)_2]Cl_2$ have been prepared and studied for anticancer and antibacterial activity. All these complexes have been characterized by UV/Visible, FTIR, NMR and Mass spectroscopy. In case of coumarins the bonding with ruthenium metal involved is carbonyl oxygen and amino/hydroxy goups. In fluoroquinolones bonding is between carbonyl and hydroxy of carboxylic acids.

The synthesized ruthenium complexes were tested against EAC (Ehrlisch's Ascitic Carcinoma) bearing Swiss albino mice. The ruthenium complexes at the dose of 2 mg/kg i.p significantly reduced the tumor volume and increased the lifespan when compared to that of control animals. Fluoroquinolones with ruthenium have retained their antibacterial activity against various Gram positive and Gram negative microorganisms.

BP 45 Synthesis and antifungal activity of benzotriazole derivatives

Sarita Pawar*, N.N. Inamdar, N.P.Jain, S.B.Wagh.

N.D.M.V.P. Samaj's College of Pharmacy, Gangapur Road, Nasik-2.

Emergence of resistant strains of microorganisms, occurrence of infection of different bacterial and fungal origin in immuno-compromised patients asks for continuous research in this context. Various derivatives of 1-hydroxybenzotriazole have been reported to posses antimicrobial, antifungal, pesticidal activity. Therefore simple derivatives like esters were synthesized and subjected to antimicrobial activity.

Substituted benzotriazoles e.g. 1-hydroxy,6-chloro-1-hydroxy,6-nitro-1- hydroxy were synthesized by refluxing ortho-chloronitrobenzene,2,5-dichloronitrobenzene and 2,4-dinitrochlorobenzene respectively with hydrazine hydrate in ethanol in presence of sodium carbonate.

The esters were prepared by using different acids in dry THF and DCC. 6-amino substituted derivatives were prepared by reduction of 6-nitro group using Raney Nickel and 6-amino (1 substituted) benzotriazole esters were synthesized.

The antifungal activity of the synthesized compounds was taken by using turbidimetric method against *Trichophyton rubrum, Epidermophyton floccosum* and *Malassazia furfur* using ketoconazole as the reference compound.

It was observed that the compounds showed moderate antifungal activity as compared to ketoconazole.

BP 46 Synthesis and antimicrobial evaluation of certain heterocycles containing sulphur and nitrogen: thiazole and triazolo-thiadiazole systems

Gopal Krishna Rao, Manzoor Ahmed, Sanjay Pai. P.N and M. Srinivasa Murthy.

Al-ameen College of Pharmacy, Hosur Road, Bangalore 560 027, Karnataka

The 1,2,4-triazoles as well as the thiazoles have shown to possess good antimicrobial activity. Certain newer thiazolyl triazolo thiadiazoles were synthesised. Out of the several derivatives synthesised 3-(2-methylthiazole-4yl-methyl)-6-(4-methylphenyl)-5,6-dihydro-s-triazolo(3,4,b)(1,3,4)- thiadiazolidine and 3-(2-methyl thiazole-4yl-methyl)-6-(4-chloro phenyl)-5,6-dihydro-s-triazolo(3,4,b)(1,3,4-)-thiadiazolidine showed good antibacterial activity in the series and 3-(2-methyl thiazole-4yl-methyl)-6-(3-methoxy-4-hydroxy phenyl)-5,6-dihydro-s-triazolo (3,4-b)(1,3,4)-thiadiazolidine and 3-(2-methyl thiazole-4yl-methyl)-6-(4-chlorophenyl)-5,6-dihydro-s-triazolo(3,4,b)(1,3,4-)-thiadiazolidine showed good antifungal activity within the series.

Ethyl ester of 2-methyl thiazole-4-acetic acid was converted to 4-Amino—3-(2-methylthiazole-4-yl) methyl-(4H) 1,2,4-triazole-5-thiol via hydrazide and dithiocarbazate salt formation.

The title compounds were synthesised by condensation of the 4-Amino—3-(2-methylthiazole-4-yl) methyl-(4H) 1,2,4-triazole-5-thiol with various substituted aromatic aldehydes using Dean Stark apparatus for the separation of evolved water. The product separated was collected after distilling off benzene. The synthesised compounds gave a characteristic TLC profile and spectral data.

The compounds synthesised were screened for antibacterial and antifungal activity by agar diffusion method comparing with Ciprofloxacin and Griseofulvin. The compounds had moderate antimicrobial activity however 3-(2-methyl thiazole-4yl-methyl)-6-(4-chlorophenyl)-5,6-dihydro-s-triazolo(3,4,b)(1,3,4-)-thiadiazolidine showed very good activity against gram negative organisms

BP 47 Synthesis and evaluation of antimicrobial activity of certain substituted 5-(β-naphthyloxy-4(substituted benzylidene amino) -3-mercapto- 4(H)-1,2,4-triazoles

Gopal Krishna Rao, Mir Hashim Ali*, Sanjay Pai P.N and Venugopala K.N.

Al-ameen College of Pharmacy, Hosur Road, Bangalore 560 027, Karnataka.

As traizoles have proven to be good antimicrobial agents, certain newer fused triazolo derivatives were synthesized and evaluated for their antimicrobial activity. Out of the several derivatives synthesized 5-(β-Naphthyloxy methyl)-4-(2-nitro benzylidene amino)-3-mercapto (4H)-1,2,4-triazole and 5-(β-Naphthyloxy methyl)-4-(5-bromo 2-hydroxy benzylidene amino)-3-mercapto (4H)-1,2,4-triazole showed good antibacterial activity in the series. 5-(β-Naphthyloxy methyl)-4-(3,4,5-tri methoxy benzylidene amino)-3-mercapto (4H)-1,2,4-triazole and 5-(β-Naphthyloxy methyl)-4-(2-chloro benzylidene amino)-3-mercapto-4(H)-1,2,4-triazole showed good antifungal activity within the series.

β-Naphthol was converted to 5(β-napthyloxy-4-amino-3-mercapto-4(H)-1,2,4-triazole) by chloroacetic

acid treatment, esterification and hydrazide formation followed by cyclization. The Schiff bases were prepared by condensation of the 5(β-napthaloxy-4-amino-3-mercapto-4(H)-1,2,4-triazole) with various aldehydes in presence of absolute alcohol.

The synthesized derivatives gave a characteristic TLC profile and spectral data.

The synthesized compounds were tested for their antimicrobial activity by agar diffusion method. Among the compounds synthesized, few compounds showed good activity against *B. subtilis* and *P. aeruginosa*.

BP 48 Synthesis and biological evaluation of 1,3,5, - trisubstituted pyrazolines bearing benzofuran

V. Harinadha Babu, S. K. Manna, Sneha, K. K. Srinivasan, G.Vijaya Bhaskara Reddy*.

Department of Pharmaceutical Chemistry, College of Pharmaceutical Sciences, MAHE, Manipal - 576 119.

Benzofuran calchones were prepared by the reaction of 2-acteyl benzofuran (1) with different aromatic aldehydes in the presence of strong base. Cyclocondensation of benzofuran chalcones with norfloxacin and mefenamic acid hydrazides resulted in the formation of benzofuran-2-pyrazolines. The structures of (3a-i) and (4a-j) were characterized on the basis of analytical and spectral data. The compounds were screened for antitubercular, antimicrobial and anti-inflammatory activities.

Anti tubercular activity was studied against *M.tuberculosis* $H_{37}Rv$ strain at 1mg, 10mg, and 100mg per ml. concentration. INH and Rifampicin were used as standards. Compound 3a was found to be active at 10mg / ml concentration level and 3b was found to be active at 1mg / ml concentration. All the other compounds were active at 100mg / ml concentration. All the compounds were studied for anti bacterial and anti fungal activities at a concentration of 500mg/ml and100mg/ml against *S.aureus, E.coli, P. aeruginosa, B. subtilis* (antibacterial) and *Candida albicans* (antifungal) by Cylinder - well method. Gentamicin and Penicillin G were used as reference standards. The compounds (3h, 3i, 4b, 4c and 4g) showed moderate activity against *S. aureus, B. subtilis* and *E. coli*. None of the compounds have shown antifungal activity. The compounds were also screened for anti-inflammatory activity by carrageenan- induced rat paw oedema method. Compounds 3a, 4c, 4e and 4j showed good activity comparable with that of the standard Ibuprofen.

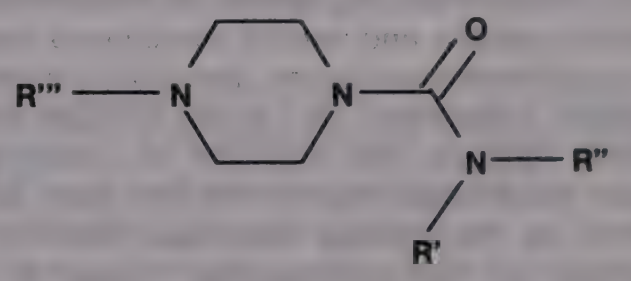
BP 49 Synthesis and anticholinergic activity of 4-alkyl/aryl piperazinyl urea derivatives

P.L. Gorde*, A.P. Pingale, R.S. Bhamber, S.B. Wagh, S.B. Kasture

Department of Pharmaceutical Chemistry, N.D.M.V.P.S's College of Pharmacy, Gangapur Road, Nashik 422002 (MS) INDIA

Piperazine salts are well known for their anticholinergic as well as anthelmentic activity. We have synthesized a library of piperazinyl urea derivatives and tested them for anticholinergic activity using rat ileum.

The primary piperazinyl urea derivatives were synthesized by treatment of potassium cyanate in presence of acetic acid. 1-alkyl/aryl piperazines were synthesized as per literature methods. Substituted piperazinyl urea derivatives were synthesized by treatment of aryl isocyanates with 1-alkyl/aryl piperazines in o-dichlorobenzene.



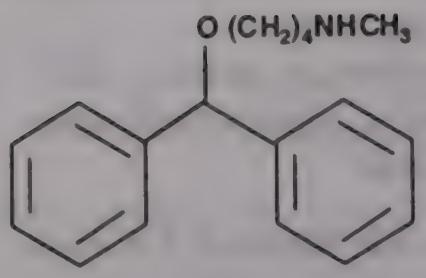
R' = R'' =H
R' = H R'' = Aryl
R''' = aryl/aryl

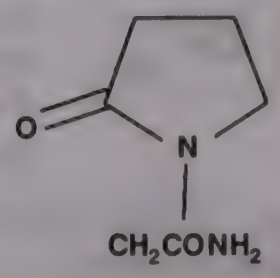
BP 50 Synthesis and pharmacological evaluation of 2-naphthyloxy derivatives as potential antiamnesic agents

Ruchi Malik*, Pooja Gupta, Harikrishna Tiwari, Dharam Paul Jindal, Poonam Piplani and Srinivaas K. Kulkarni

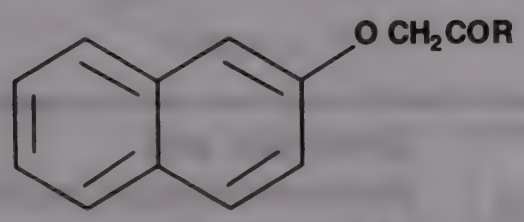
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh 160 014

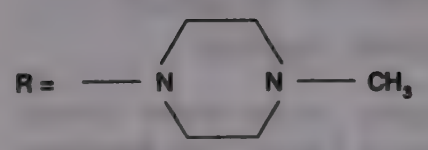
Nootropics are a heterogeneous group of compounds of diverse chemical composition and biological function that allegedly facilitate learning and memory or overcome natural or induced cognitive impairments. Deficits in cognitive and memory performance observed are due at least in part to deficient cholinergic functioning. The nootropics bifemelane (I) and

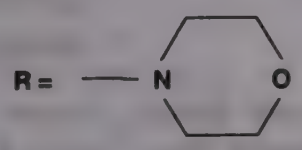


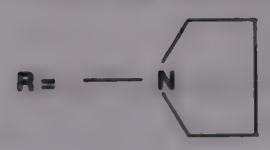


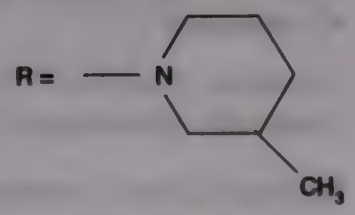
piracetam (2) demonstrate certain structural resemblance to various cholinergic compounds in containing one hydrogen bond acceptor moiety and a basic nitrogen. Spurred by a concern for treating the normal and pathological deficits in memory and cognitive performance the use of drugs to facilitate cognition, learning and memory is a lively area of current research. The survey has enlisted the aryloxy derivatives, 2-pyrrolidinone derivatives, dimethylaminoethylethers and their carboxamide derivatives and arylaminoethoxyethanols, etc. as some of the series with antiamnesic activity and urged to explore these in the possibility of getting better bioactive compounds. In the light of the above postulates the present research work was designed to synthesize 2-naphthyloxy derivatives employing the acyclic / heterocyclic ring system *(N,N*-dimethylamine, *N, N*-diethylamine and various cycloamino moieties such as *BN*-methylpiperazine, pyrrolidine, piperidine, morpholine, 3-pipecoline, etc.) as the hydrogen bonding acceptor function and insertion of $-OCH_2$-group between the aromatic ring and the side chain using 2-naphthol as the starting material 2-Naphthol was condensed with methylchloroacetate followed by fusion with different amines to give target compounds **3a-3f**.

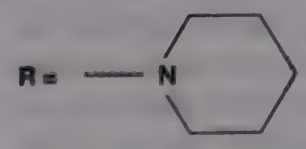












The compounds synthesized pharmacological investigations have been found to possess significant antiamnesic activity when compared with piracetam. Compounds **3b, 3d, 3f** showed dose dependent antiamnesic effect with a peak effect at 5 mg/kg.

CP$_1$ Phytochemical screening, standardization and anti-microbial activity of Shilajit

Indu Sahrawat, Mohd. Ali and Onkar Singh*

Department of Pharmacognosy & Phytochemistry, Faculty of Pharmacy, Jamia Hamdard (Hamdard University), New Delhi 110062.

Shilajit (Asphalt), a blackish-brown exudation obtained from the steep rocks has been used for ages in traditional medicines in the treatment of bronchial asthma, diabetes, genito-urinary infections and stomach ulcers.

The present study involves the isolation of the chemical constituents by chromatographic techniques and their characterization (by TLC, UV, IR, NMR, Mass spectrometry). The phytochemical screening of Shiliajit resulted in isolation of six compounds, i.e., Shilajityl acetate, Shilajitol, Pyrochatechol, Shilacetichol, Shilaxanthone and Shilanthranil and their stereostructures have been elucidated as 3-acetoxymethylene-7-methyl-4a, 5a, 6a nonatriol, 6-(9, 9-dimethylbutyl) phenol, 1, 2-dihydroxybenzene, 1-cyclohexyl-3, 4-dihydroxybenzene, 2, 3, 12, 13-tetrahydroxy-10, 15[a,f]-phenyl-17-one and 2, 3, 13, 14-tetrahydroxy-15, 16-[a,f]-phenyl-7H-antracen-18-one on the basis of chemical data analyses and chemical reactions.

The standardization parameters studied included preliminary phytochemical analyses, TLC profile of petroleum ether, chloroform and methanol extracts, ash values, successive extractive values (in petroleum ether, benzene, ethyl acetate and methanol) and loss on drying.

The alcoholic extract of shilajit exhibited antimicrobial activity against *S. aureus and E. coli.*

CP$_2$ Standardisation of *Camellia sinensis* by modern techniques

N. Mahadevan, R. Meenakshi, N.G. Vijayalekshmi* and B. Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund-643001, The Nilgiris, Tamilnadu

Green tea is obtained from leaves of *Camellia sinensis* (Family: Theaceae) by air-drying. It is reported to possess hypolipidemic activity. It reduces cholesterol, blood pressure, risk of cancer and heart diseases. It contains caffeine and polyphenols. Caffeine content of green tea was estimated by HPTLC method and polyphenols was estimated by spectrophotometric method. Green tea was extracted with water by maceration. The extract showed the presence of tannins and caffeine. Polyphenol content was estimated by spectrophotometric method using gallic acid as a standard. Extract was dissolved in 10 ml of water and various dilutions were prepared. Phenol content was estimated after adding Folin ciocalteu's reagent and 20% sodium carbonate. Phosphomolibdic acid in Folin ciocalteu's reagent reacts with Polyphenols in alkaline medium produce a blue coloured complex. The complex was measured at ë max of 643 nm. Calibration curve for gallic acid was made. Polyphenol content was found to be 8.1% in green tea. Caffeine in Camellia sinensis crude extract was estimated by HPTLC. 10mg of caffeine was dissolved in 10ml methanol and various concentrations of solutions were prepared. 100mg of crude extract of Camellia sinensis was dissolved in 10 ml methanol and different volumes were applied on to the HPTLC plates using LINOMAT IV TLC applicator. Ethyl acetate, methanol and water (100:14:5) was used as solvent system. Plates were observed under UV light and scanned at a wavelength of 273 nm. The spectrum of caffeine was recorded. The linearity range was found to be 200 to 2000ng. The limit of detection and limit of quantification were found to be 60ng and 180ng. The percentage of caffeine was found to be 5.03 %.

CP$_3$ Estimation of Valeric acid in *Valeriana wallichii* by HPTLC technique

S. Manimaran, S. Sudhakar Raja*, M.J. Nanjan and B. Suresh

Department of Phytopharmacy and Phytomedicine, TIFAC CORE (HD), J.S.S College of Pharmacy, Ootacamand.

A simple and reproducible HPTLC technique for the estimation of valeric acid in *Valerian wallichi DC* was developed and described. The root of *Valeriana wallichii* (Indian Valerian) is used for nervous excitability, insomnia, gastrointestinal spasms, epilepsy, neurosis and rheumatism. The dried roots of *Valeriana wallichi* were macerated with ethanol for 48 hours and the extract was prepared by concentrating it below 40°C. The standard valeric acid and 20mg/ml solution of the extract was spotted on precoated HPTLC silica gel GF 254 plates and the chromatogram was developed using the solvent system Toluene: Ethyl acetate: Glacial Acetic acid (65: 35: 0.5). The plate was scanned at 254 nm by absorption mode and estimated for valeric acid. The valeric acid content in the *Valeriana wallichi* extract was 27.7% v/w. The sensitivity of the proposed method was 0.1ml. The linearity of valeric acid was observed in the range of 1ml to 10 ml and the correlation coefficient of linearity was 0.999. The recovery value of valeric acid by standard addition method was 99.1%. The proposed method being precise, sensitive and reproducible can be used for quantification of valeric acid in *Valeriana wallichi.*

CP$_4$ *In-vitro* production of hepatoprotective and cardiac inhibitor compounds in biomass of different cultures of *Eclipta Alba Linn.* and *Silybum marianum gaertn.*

Sagar B.P.S* and Kalia A.N.

*Pharmacognosy Division, Faculty of Pharmaceutical Sciences, Maharshi Dayanand University, Rohtak - 124 001. Haryana

Excised explants of aseptically geminated seedlings of *Eclipta alba Linn* and *Silybum marianum* (milkthistle) were cultured *in vitro* on Murashige and Skoog's (MS) medium supplemented with different combinations and concentrations of auxins and cytokinins for the development of biomass. Calli of fourth passage were cultured on MS medium for suspensive culture studies. The *in-vitro* produced hepatoprotective and cardiac inhibitory compounds were extracted, isolated, purified and characterized and investigated pharmacologically. Single dose of carbon-tetrachloride (CCl_4) (1.5ml/kg/day p.o) was administered in *albino Wistar* rats to induce hepatotoxicity which was characterized by significant reduction in urinary ascorbic acid excretion rise in serum transaminases (SGPT, SGOT), albumin, globulin, total protein, billirubin and alkaline phosphatase. Different extracts containing active principles and purified compounds were administered orally at various doses for one week. Treatment with different extracts alleviated the serum enzyme activities, increased urinary excretion of ascorbic acid. Histopathological studies and liver weight analysis showed significant recovery. Hepatoprotective effects of extracts and purified compounds were also compared with standard reference drugs i.e. pure Silymarin and "Sivylar" well known Indian hepatoprotective phytoformulation). Their mechanism of action for the activity was also established. Cardiovascular investigation of various extracts was performed on isolated frog heart. Extract of *E. alba* produced negative inotropic and chronotropic effects on frog heart due to which cardiac out put was reduced. *E. Alba* suspension culture and callus extract produce comparatively higher cardiac inhibitory activity than leaves extract.These extracts had also antagonised the effect of adrenaline and showed anti-adrenergic effect.

CP$_5$ Phytochemical investigation and pharmacological studies of *Capparis sepiaria* root

Ram Bindurani*; Haryani N.B; Bhope S.R; Rangari V.D.

B.V.D.U. Poona College Of Pharmacy, Erandavane, Pune- 411038

Capparis separia Fam. Capparidaceae (Hindi– Kanthari) is much branched, woody shrub distributed throughout India. It is reported to have stomachic and antipyretic

Properties .A decoction of its roots is inhaled as remedy for chest pain. There has no work been reported on the plant. Hence, the roots of *C.separia* have been selected for phytochemical investigation and pharmacological studies.

Dried roots of C. separia were successively extracted with chloroform, methanol and water. Methanolic extract has shown a positive test for alkaloids. Methanolic extract was subjected to column chromatographic fractions, which afforded an alkaloid coded as NH-1. NH-1 has been structurally elucidated by spectral means as a novel Pyrrolidone alkaloid for which a name sepiarine chloride has been proposed.

Methanolic extract and NH-1 has been subjected to hypotensive activity using Dog Blood Pressure Model. Both methanolic extract and NH-1has shown a dose dependent fall in blood pressure. Effect of methanolic extract and NH-1 was found to be more prominent.

Methanolic extract showed a marked antimicrobial activity against *S. aurius, Serrate, B.subtilis, K.pneumoniae* and *P.vulgaris*. The methanolic extract has shown a very poor anti-inflammatory activity when studied on carrageenan induced rat paw oedema model.

CP$_6$ Phytochemical and pharmacological investigation of *Embelia. ribes Burm. fruits*

Kashiful Haq, Mohd. Ali, Abdul Wadood*, Onkar Singh, Showkat R. Mir & Reni Kapoor

Department of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi-110062

The dried ripe fruits of *Embelia ribes Burm.*, commonly known as Vidang, are found in hilly parts of India from the central and lower Himalayas down to Sri lanka and Singapore. It is useful in tumour, ascites, bronchitis, mental diseases, dyspnaea, disease of the heart, urinary discharges Phytochemical investigation

of an ethanolic extract of E. ribes resulted in the isolation of embelin, embelinol, embeliaribyl ester and embeliol. Their structures have been elucidated on the basis of spectroscopic data analyses and chemical means. Neuropharmacological evaluation of ethanolic extract of the fruits of E. ribes, suspended in tween-80 suggested the drug to have anticonvulsant effect and good antidepressant activity at a dose of 200mg / kg on male albino mice.

CP$_7$ Comparative antioxidant activity of some herbal extracts

N. H. Indurwade, S. B. Kosalge, S.P. Pakhale V. V. Redasani, Rajendra Khade*

S.N. Institute of Pharmacy, Pusad . Dist. Yavatmal Pin:- 445 204

Ethnobotanical search reveals use of many traditional herbs as an effective way of preventing cancer by preventing oxidative damage. A method based on reduction of methanolic solution of colored free radical DPPH was used to determine the free radical scavenging activity. The decrease in absorbance of DPPH as its absorption maxima of 516 nm is proportional to concentration of free radical scavenger added to DPPH reagent solution. The study shows that more or less all the aqueous extract of *Allium sativum. Berbares aristata, Glyceriza glabara, Gingko biloba and Lawsonia inermis* possesses the antioxidant activity when compare with the sodium meta-bisulphate From EC_{50} value *Glyceriza glabara,* shows comparatively better antioxidant activity than *Berharis aristata, Lawsonia inermi s, Allium sativum, Gingko biloba.*

CP$_8$ Hypoglycemic acitivity of some *Ethno-botanical* plants in albino rats

Indurwade N. H. , Biyani K.R. , Kadam V.N., Chhajed M.R.*

S.N. Institute of Pharmacy, Pusad . Dist. Yavatmal Pin:- 445 204

In Umerkhed region (Vidharbha), some plants like Bijja sal [*Pterocarpus marssupium* (Leguminosae)], Pandhri tilwan [*Cleome gynandra* (Capparidaceae)]and Nay [*Enicostima axillari* (Gentianaceae)]are traditionally used by local Vaidya for the treatment of Sakhar Bimari (Diabetes Mellitus). In present preliminary study an attempt has been made to evaluate the hypoglycemic activity of these plants in systemic and scientific manner.

In present study the suspension of Bijja Sal, Pandhri tilwan and Nay powder were prepared in distilled water using 1% gum acacia as suspending agent. The prepared suspensions were administered to the albino rats at the dose of 200mg/kg of the body weight. The glucose level before and after the drug treatment was noted by using digital glucometer (Accu-check).

The result showed marked hypoglycemic activity with all plants in albino rats. *Pandhri tilwan [Cleome gynandra* (Capparidaceae)] powder showed greater activity than Bijja sal [*Pterocarpus marssupium* (Leguminosae)] powder , and Nay [*Enicostema axillari* (Gentianaceae)] powder. The study of active chemical constituents responsible for hypoglycemic activity is in progress.

CP$_9$ Antioxidant activity of *Syzygium cumini* fruit peel extract in different *invitro* models

***Priya S.[1], Uma D. Murthy[1], Shashidhara S. [1], Bhagyalakshmi N.[2], Narayan M.S.[2]**

1. Department of Pharmacognosy, Govt. College of Pharmacy, Bangalore.
2. PCBT Department, CFTRI, Mysore.

Oxidative damage remains an inescapable outcome of aerobic existence. Reactive oxygen species are involved in damaging DNA, carbohydrates and proteins leading to the development of many diseases such as aging, arthritis, cardiac diseases and cancer. Antioxidants prevent or delay the development of these diseases and may be natural or synthetic. Natural antioxidants are gaining more importance as they are safe and our nature is rich in these constituents and are present in different parts of the plants.

The plant *Syzygium cumini* (fam: Myrtaceae) is native of India commonly known as jambolan. Different parts of the plant are widely used since ancient times for numerous medicinal purposes mainly as astringent, stomachic, diuretic and used in diabetes, anemia and asthma. The fruits of the plant being edible are widely available and are cheaper. The peels of the fruit are rich in anthocyanins and other phenolics.

The aim of the present study was to assess the antioxidant activity of fruit peel extract by *invitro* methods on different tissue models and to findout its suitability as antioxidant agent.

The fruit peels separated and extracted with acidified 70% ethanol, centrifuged and concentrated. Antioxidant activity of the extract was studied by investigating the inhibition of lipid peroxidation in rat liver homogenate and liver mitochondrial preparation by thiobarbituric acid test (TBA) (Ohkawa 1979) and free radical scavenging activity by DPPH method (Hatalo T. 1988) and reducing power activity of the extract was determined by treating with trichloroacetic acid and ferric chloride and measuring the absorbance at 700 nm (Oyaizu 1986). The extract exhibited increase in antioxidant activity with increase in concentration. The extract has shown 83% and 86% protection by TBA test and 92% free radical

scavenging activity by DPPH method at a concentration of 5 mg equivalent of peel and there was considerable increase in reducing power with increase in concentration of the extract.

The antioxidant activity of the extract in all *in vitro* models studied was comparable. Hence the fruits of *Syzygium cumini* could be considered as neutraceutical with potent antioxidant activity.

CP$_{10}$ Standardization and hypoglycemic activity of *Pterocarpus marsupium* Roxb. (Vijasaar).

S H Ansari, H M Mukhtar* and M Ali

Dept. of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi-62

Diabetes is a chronic disease characterized by high blood glucose levels due to absolute or relative deficiency of circulating insulin levels. Though different types of oral hypoglycemic agents are available along with insulin for the treatment of diabetes mellitus, there is increasing demand by patients to use the natural products with antidiabetic activity. Insulin cannot be used orally and continuous use of the synthetic drugs causes side effects and toxicity. Herbal drugs are prescribed widely even when their biologically active compounds are unknown, because of their effectiveness, less side effects and relatively low cost.

Preliminary phytochemistry and fluorescent analysis were carried out as per the standard procedures.

Total ash, (5.2), Water-soluble ash, (4.5), Acid insoluble ash, (3.8), Extractive Values (Successive), Petroleum ether soluble (25.24), Benzene soluble, (3.16), Chloroform soluble, (10.5), Ethyl Acetate soluble, (18.90), Methanol soluble, (29.28), Cold Maceration, Petroleum ether soluble, (20.13), Benzene soluble, (4.93), Chloroform soluble, (8.86), Ethyl Acetate soluble, (3.6), Methanol soluble, (8.33). Foreign matter, (2.05). Macroscopic characters: Shape; Irregular, Size; Variable, Thickness; 3-5 mm, Fracture; Difficult to break, Taste; Astringent, Colour; Golden brown to Reddish brown, Odour; None, Texture; Tough, Very hard. Microscopic characters: T.S, T.L.S and R.L.S. showed: Fibres; Vessels; Xylem parenchyma; Calcium oxalate crystals; Medullary rays. Fluorescent analysis in UV and ordinary light at 254 and 366 nm. in different organic and inorganic solvents like Methanol, Ethanol, P. ether, Benzene, Chloroform, Acetic acid, Hydrochloric acid, Sulphuric acid, Nitric acid, Picric acid, Iodine, $FeCl_3$, NaOH. Powdered drug reaction with different chemicals; HCl, HNO_3, H_2SO_4, CH_3COOH, Picric Acid, I_2, NaOH etc. Phytochemical investigations for Alkaloids, Glycosides, Saponins, Tannins, Proteins, Carbohydrates, Acids, Phenols, Flavonoids. Hypoglycemic activity of the ethanolic extract of *Pterocarpus marsupium Roxb.* wood. The ethanolic (95%) extract of wood was studied for hypoglycemic activity in alloxanised albino rats of either sex, weighing 180-200 g. They were maintained under standard environmental conditions and had free access to feed (Hindustan Lever, India) and tap water ad libitum during the quarantine period. The animals were fasted for 16 h before experiment but allowed free access to water. The effect of ethanolic wood extract on serum glucose level of rats was studied by glucose oxidase method. In alloxan induced diabetic rats, ethanolic extract showed significant ($P< 0.01$) and considerable fall in blood glucose level.

CP$_{11}$ Evaluation of hepatoprotective activity of methanolic extract of the bark of *Ficus racemosa* Linn (Moraceae)

R. Bhaskara Rao*[1], S. C. Mandal[2], M. Pal[2] Arunachalam[2], Suba[2]

1. Sultan-Ul-Uloom College of Pharmacy, Road No 3, Banjara Hills, Hyderabad. 34 A.P.
2. Department of Pharmaceutical Technology, Jadavpur University, Kolkatta - 32

The stem bark of *Ficus racemosa* Linn. (Moraceae) is well - known plant, known as 'Gular', 'Umbar' or 'Jagyadumbar' (Anonymous, 1952) is found throughout India. *Ficus racemosa* is very useful in treating several liver disorders (Chopra et al, 1958; Kirtikar and Basu 1975; Nadkarni et al, 1976)

CCL4 - induced hepatotoxicity was carried out CCL4 in liquid paraffin (3 ml kg) (Chun Ching et al., 1995).Animals were randomized into four groups of six rats each. First group (control) received normal saline 1.0 ml kg (p.o.). Second group received CCL4. Third group received CCL4 and MEBFR (400 mg/kg, p.o.) Fourth group received CCl4 and a standard liver tonic *Neutrosec* (5ml/kg), p.o.). Maity et al, 1997). All the animals were given one day alternative treatment for a period of 4 weeks.

Paracetamol- induced hepatotoxicity was done in rats (Jollow et al, 1973, Dwivedi et al, 1991). Animals were randomized into four groups of six rats each. Group I received normal saline 1.0 ml/kg, p.o.). Group III and Group IV were given MEBFR (400 mg/kg, p.o.) extract and *Neutrosec* (5 ml/kg) respectively for a period of seven days. On seventh day paracetamol suspension (750 mg/kg, p.o.) was given to group II animals and to group III and group IV animals (Hiroshi et al, 1987).

MEBFR (400 mg/kg, p.o.) exhibited a significant ($p<0.01$) reduction in CCL4 and paracetamol induced levels of SGOT, SGPT, Alkaline phosphatase and serum bilirubin concentration. The results were comparable to that of the standard *Neutrosec*. The

results established Pharmacological evidence as Hepatoprotective agent and thereby it substantiated the folklore claim.

CP 12 Influence of growth hormone on bioproduction of andrographolide in cell cultures of *Andrographis paniculata* Nees

Anurag R.*, Manjunath Setty and K. Balaji

College of Pharmaceutical Sciences, Manipal-576119

Kalmegh, *Andrographis paniculata Nees*. (Acanthaceae) is well known for Indian system of medicine 'Ayurveda'. It is very potent hepatoprotective and bitter. Boorsma (1896) isolated andrographolide from different part of the plant of *Andrographis paniculata*. Andrographolide is a chemically diterpenoid lactone. It has potent hepatoprotective, antimalarial, immunostimulant and consequently there is a much current interest in its use as a natural hepatoprotective and immunostimulant. MS medium supplemented with Dicamba (2 mg/l), kinetin (1mg/l) and sucrose (3% w/v) was found suitable for initiation and maintenance of cell cultures of A.paniculata.

The cell cultures, after 10 days were withdrawn and the total broth (cells and medium) of each culture flask were extracted for andrographolide. MS media supplemented with Dicamba (2mg/L) and Kinetin (1mg/L) has shown maximum amount of bioproduction of andrographolide (7.67± 0.87 mg/L) in cell cultures over that of other hormonal combination (NAA 2mg/l and kinetin 1.0 mg/l).

CP 13 Hepatoprotective activity of *Moring oleifera* Lam

K. Hemalatha H*, Nataraj and H.M. Suresh

Dept of Pharmacognosy, S.A.C. College of Pharmacy, AIMS Campus, B.G.Nagar-571448. Mandya (D). KAR.

The plant *Moringa oleifera* lam (Moringacea) is found throughout India and Burma. The whole plant is used as multipurpose like food and as a tradicitional use in Ayuveda and Sidhha system. The ethanolic extract of leaves of *Moringa oleifera* and their two different crude fractions, petroleum ether (40-60°) and solvent ether, were subjected to preliminary qualitative chemical investigation. The ethanolic extract and other fractions were screened pharmacologically for their hepatoprotective activity. The ethanolic extracts and solvent ether fractions have shown significant activity by lowerining the enzymes levels like GOT, GPT and histological study of liver tissue shows normal artichitecture with mild fatty change in rats treated with CCl_4 when compared to control and standard LIV-52 treated rats.

CP 14 Investigation of anticancer activity on leaves of *Emilia sonchifolia,* Linn

S. Vijayalakshmi*, Ansa Mathew, N. Mahadevan and T.K. Ravi

Department of Pharmacognosy and Phytochemistry, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Emilia sonchifolia, Linn (Family: Compositae) is known as hiran khuri, used as astringent, antipyretic, antiasthmatic, in rheumatism, cough, cuts and wounds and in diarrohea. The plants belong to family Compositae are reported to have anticancer properties. *In vivo* and *in vitro* studies were carried out to screen the anticancer activity against cancer cell lines and in mice. The dried leaves were extracted with petroleum ether, benzene, ethyl acetate and ethanol successively. The dried extracts were used for the anticancer screening at various concentrations. *In vitro* studies were carried out by trypan blue exclusion method using Dalton's lymphoma ascites (DLA) and Ehrlich ascites carcinoma (EAC) cells. The extracts were dissolved in dimethyl formamide and various concentrations of the extract solutions in the range of 10, 25, 50 and 100µg/ml were prepared and subjected for anticancer screening. *In vivo* studies were carried out to assess the reduction of solid tumor in mice. *In vivo* studies were carried out using DLA cells. The extracts were suspended in 0.5% Carboxy methylcellulose and administered to the mice at a dose of 200mg/kg body weight for 10 days. Tumour cells were aspirated from the peritoneal cavity of the tumour bearing mice. Tumour volume was calculated. It was found that, the ethanol and benzene leaf extracts showed significant anticancer activity against DLA cells, but their activity against EAC cells was low. The ethyl acetate leaf extract showed lesser activity against DLA cells when compared to ethanol and benzene leaf extract. In the assessment of solid tumour reduction in mice, it was found that the percentage inhibition produced by the ethanol leaf extract was higher than benzene leaf extract. The percentage inhibition of ethanol and benzene extract was found to be 94.4 and 79.4 respectively.

CP 15 Antiulcerogenic activity of the various extracts of *Dodonaea viscosa* (L). Jacq., Leaves

Veerapur. V. P*, Badiger. A. M, Joshi. S. D Shastry. C. S.

Department of Pharmaceutical Chemistry, S. E. T.'s College of Pharmacy, Dharwad-2.

Dodonaea viscosa (L). Jacq., popularly known as 'aliar' and 'vilayati mehandi' in India, is an evergreen shrub abundantly available in Western Ghats of Karnataka, India. The species has been used in traditional medicine for the treatment of simple ulcer, fracture, snakebite, sore and painful gum and teeth for immediate relief. Lack of scientific data to support the folklore claims, prompted us to study the antiulcerogenic activity of leaves of *D. viscosa.*

The coarse powder of the leaves of *D. viscosa* was used for sequential extraction with different solvents in their increasing order of polarity. The extracts obtained were petroleum ether (60°-80°) extract, benzene extract, chloroform extract, acetone extract, ethyl acetate extract, ethanol extract and chloroform: water extract. The dried extracts were subjected to various chemical tests to detect the different phytoconstituents. Selected extracts based on phytochemical screening were used for antiulcerogenic studies.

Antiulcerogenic activity was evaluated using three different assay models. Aspirin plus pylorus-ligation and administration of indomethacin and ethanol in different set of animals were employed for induction of acute gastric mucosal lesion.

A preliminary phytopharmacological investigation of ethanol extract of *D. viscosa* leaves revealed the presence of flavonoids, tannins, sterols and saponins and showed promising anti ulcer activity. In view of this we conducted a bioactive-guided fraction studies of *D. viscosa* using various experimental gastric ulcer models and offensive and defensive gastric mucosal factors in rats. Among the tested extracts ethyl acetate extract exhibited significant protection of ulcers in all experimental models and increased serum calcium level, decreased alkaline phosphatase activity in indomethacin-induced ulcer model. The antiulcer activity of the extracts may be attributed to cytoprotective and healing activity of flavanoids. Determination of exact mode of action and further activity-guided fraction study are the subject of our further research interest.

CP 16 TLC densitometric method for the quantification of eugenol and gallic acid in clove

K. Niranjan*, Sachin Pathak, Harish Padh and M. Rajani

B. V. Patel Pharmaceutical Education and Research Development, (PERD) Centre, Thaltej, Ahmedabad – 380 054

Eugenol and gallic acid are reported from the flower buds of *Eugenia caryophyllata Thunb.* (clove). Both the compounds have been shown to give interesting biological activities and hence can serve as biomarkers. We report a simple TLC densitometric method for the quantification of eugenol and gallic acid in clove.

Samples of clove were collected from three different geographical locations and methanolic extracts were prepared. Toluene-ethyl acetate-formic acid (3 : 2 : 0.4 v/v) was used as the mobile phase to resolve the compounds and the TLC plates were scanned at 280 nm using CAMAG TLC Scanner. The method was validated for precision, repeatability and accuracy.

The method was found to be precise with RSD of 0.61 and 1.3 (intraday) and 0.96 and 0.24 (interday) for different concentrations of eugenol and gallic acid respectively. Instrumental precision was 0.24 and 0.21 (% CV) for eugenol and gallic acid respectively. Accuracy of the method was checked by conducting recovery study at two different levels for eugenol and gallic acid and the average percentage recoveries were found to be 99.79 % and 97.90 % respectively. The contents of eugenol and gallic acid in different samples of clove, as estimated by the proposed method, were found to be in the range of 12.9-14.6 % and 0.31-0.61 % respectively.

The proposed TLC densitometric method for the estimation gallic acid and eugenol was found to be simple, precise, specific and accurate and can be used for standardization of the clove samples and for their routine quality control.

CP 17 Study of phytochemical constitutents of *Cardiospermum halicacabum* Linn

Sundaraganapathy R*, Nagarajan M, Muthumani P, Jayaraman S[1], Sivakumar R[1], Prakash A[1]

K.M. College of Pharmacy, Madurai, [1]Shoba College of Pharmacy, Erode, Tamil Nadu

The aerial parts of *Cardiospermum halicacabum* Linn. were studied for its phytochemical profile. The plant is used in rheumatism, lumbago and nervous disease.

The aerial parts of *Cardiospermum halicacabum* Linn. was examined for phytochemical properties. 750 g of air dried powder was extracted completely with ethyl acetate and the extract was concentrated, neutralized (pH 7). The ethyl acetate extract was chromatographed over silica gel column. Yellow crystalline powder was obtained from ethyl acetate - acetone (50:50) eluate. The compound was identified that may be a flavonoid as flavone containing phenyl hydroxyl and alcoholic hydroxyl groups by its melting point (345-350°C). Rf value (0.833, 0.892, 0.884 in various mediums), solubility (in dil. KOH), IR spectrum (peak at 3300, 581-950, 750-800, 1240, 1440 cm^{-1}), NMR spectrum (signals from 6.5-7.9 δ) and UV spectrum (250-300 nm &λmax290nm).

A second compound was identified as a yellow crystalline powder by the recolumn chromatography of acetone-methonal (75:25) eluate at the fraction of 100% acetone. It was identified that may be a flavonoid as a flavone containing substituted phenyl hydroxyl and alcoholic hydroxyl groups by its melting point (290-300°C), Rf value (0.769, 0.821, 0.898 in various mediums), IR spectrum (peak at 3290, 580-950, 715-800, 950, 1275, 1441 and 1014 cm^{-1}) NMR spectrum (signals at 6.5-7.9 and 3.6 δ) and UV spectrum (250-290 nm, λmax280nm).

These two compounds gave strongly positive reactions for flavonoids by shinoda test and other test for flavonoids.

It is reported that two flavonoids were identified from *cardiospermum halicacabum* Linn.

CP$_{18}$ A rapid densitometric method for the quantification of luteolin in medicinal plants using HPTLC

Srinivasa H*., Milind S Bagul, Padh. H, Rajani. M

B. V. Patel Pharmaceutical Education & Research Development (PERD) Centre, Thaltej, Ahmedabad 380 054

Luteolin, a natural flavonoid, was shown to have important biological activities. It exhibited spasmolytic effect, anti-histaminic activity, capillary strengthening activity. It has strong antioxidant potential, and it is an active inhibitor of different hyaluronidases. Luteolin is an important dietary cancer preventive agent. Luteolin has been reported to be present in many important medicinal plants including *Cuminum cyminum* Linn., *Bacopa monnieri* (L.) Pennell, *Achillea millefolium* Linn. We present a sensitive HPTLC method for the quantification of luteolin from the above plant materials. The method was validated for precision, repeatability and accuracy. The method was found to be precise with RSDs for intraday in the range of 0.77-1.29 % and inter-day in the range of 1.02-2.08 %. Instrumental precision and repeatability of the method were found to be 0.39 and 0.57 (% CV). Accuracy of the method was checked by recovery study conducted at two different levels and the average percentage recovery was found to be 100.92 %. By this method it was possible to detect and quantify even very small quantities of luteolin present in the raw materials e.g. 0.006 % in B. monnieri. The amount of luteolin was found to be 0.006 to 0.03 % w/w in the above samples.

The proposed TLC densitometric method for the quantification of luteolin was found to be simple, precise, specific, sensitive and accurate and can be used for quality control of raw materials. As the developed method is simple and it requires minimum sample clean up, it can be adopted for quantification of luteolin in herbal drugs and its formulations.

CP$_{19}$ Antioxidant activity of *Aporosa lindleyana root*

Shrishailappa Badami*, Sujay R Rai, Jagadish P.C. and Suresh B

Department of Pharma Chemistry, JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

Ethnomedical literature contains a large number of plants that can be used against diseases, in which reactive oxygen species and free radicals play a major role. Several plants are known to possess strong antioxidant properties. A decoction of the root of *Aporosa lindleyana* is used traditionally in jaundice, fever, headache, insanity, seminal loss and excessive thirst. The 50% ethanol extract of Aporosa lindleyana exhibited hypoglycemic, diuretic and hypothermic activities. In the present investigation various extracts of *Aporosa lindleyana* root were screened for the *in vitro, in vivo* antioxidant activity using standard procedures.

Four successive and two crude extracts of *Aporosa lindleyana* root were tested for antioxidant activity using standard *in vitro* and *in vivo* models. The successive methanol and ethyl acetate and crude 50% methanol extracts showed antioxidant activity with IC_{50} values 3.51 ± 0.27, 6.09 ± 1.00 and 7.34 ± 0.46 µg ml, respectively in DPPH method. In the nitric oxide radical inhibition method, the successive ethy1 acetate, petroleum ether and methanol extracts showed antioxidant activity. The successive methanol extract at 100 and 200 mg/kg body weight administered for five days prior to CCl_4 treatment caused a significant increase in the levels of catalase and SOD and a significant decrease in the level of TBARS in liver, kidney and blood, when compared to CCl_4 treated control. These results indicate strong antioxidant nature of *Aporosa lindleyana* root. The *in vitro* cytotoxicity studies against normal Vero cell lines indicate nontoxic nature of the root extracts. The study provides a proof for the ethnomedical and reported biological activities.

CP$_{20}$ Phytochemical and cytotoxicity studies on the leaves of *Coccinia grandis* Linn

N. Krishnaveni*, P. Ramalingam, Mohamed Halith, T.K. Ravi

College of Pharmacy, Sri Ramakrishna Institute of Pharmaceutical Sciences, Coimbatore 640 044, TN

In many countries the herbal therapy has been the subject of interest as it is of low toxicity and potency. *Coccinia grandis* Linn is a perennial, much branched tendril climber belonging to family Cucurbetaceae. The plant has been claimed to treat

leprosy, skin diseases, intermittent fever, asthma, cough and jaundice. But no phytochemical and pharmacological studies has been done on the leaves of *Coccinia grandis* Linn. Thus the aim of this work is to investigate phytochemically and also to carry out cytotoxic studies by Tryphan blue exclusion method.

The leaves were shade dried and coarsely powdered. The powder was then extracted with petroleum ether, alcohol and dichloromethane by continous hot extraction method. The extractive values were noted. The dichloromethane extract was subjected to qualitative chemical tests and thin layer chromatographic studies. The solvent system used for TLC study was chloroform: methanol at a ratio of 95:5 and the spots were visualized by spraying Vanillin Sulphuric acid reagent. Invitro cytotoxic study of dichloromethane extract was carried out against Dalton's lymphoma ascites tumor cells at different concentrations ranging from 100-1000mgm. The LD_{50} of the extract was determined by Tryphan blue exclusion method.

The phytochemical investigation of the DCM extract revealed the presence of carbohydrates, proteins and Terpenes. The LD_{50} dose of the dichloromethane was found to be between 800-900mgm

CP$_{21}$ Anticancer activity of *Indigofera aspalathoides* against Ehrlichs ascites carcinoma in swiss albino mice.

Vimal Kumar Varma. M*, Hemamalini. K, Karpagam Kumara Sundari.

Smt. Sarojini Ramulamma College of Pharmacy A.P., Periyar College of Pharmacutical Science for Girls, Trichy.

Indigofera aspalathoides Vahl. ex.Dc. (Papilionaceae) is a well known for its anti-inflammatory, analgesic, anti ulcer, Sedation activities and widely used to treatment of various ailments. In ayurvedic system of Medicine the decoction of this Medicinal herb is useful in the treatment of Leprosy, swelling, headache and as anti dermatophytic. The present investigation was carried to evaluate the anti cancer potential of Methanol extract of *Indigofera aspalathoides* against Ehrlich's ascites Carcinoma in Swiss altino Mice.

The life span, tumour volume and hematological parameters were estimated in the treated and the untreated mice. The methanol extract at the dose of 150mg/kg significantly increased the life span, reduced the tumor volume and restored the altered hematological parameters when compared to that of the untreated control animals. Further investigation is underway to determine the exact mechanism and to isolate the exact Phytoconstituent that is responsible for the anticancer activity.

CP$_{22}$ Pharmacognostical standards for *Bixa orellana*

Rani.S., Padmaja.V.* and Velayudha Panicker,P.

College of Pharmaceutical Sciences, MedicalCollege, Thiruvananthapuram-695 011, Kerala

Bixa orellana (Annatto tree) is a small, handsome, evergreen tree. The fruit is an ovoid capsule containing 15-20 seeds embedded in a slightly red pulp. It is mainly used as a food colorant. Although mostly only the seed paste or seed oil is used today, the Rainforest Tribes have been using the entire plant as medicine for centuries. It is an antipyretic, astringent and useful in intermittent fevers and gonrrhoea. The present work is an attempt to carry out the pharmacognostical and preliminary phytochemical studies of the seeds.

The organoleptic and microscopical characters of the air dried powdered seeds were carried out. The characters of the powdered seeds were studied microscopically and the dimensions of the different tissues were calculated. Successive solvent extraction with solvents of increasing polarity was done and qualitative phytochemical tests on different extracts were also carried out. The TLC and HPTLC patterns of different extracts were examined.

The organoleptic features of the seeds and histological characters after staining with phloroglucinol-hydrochloric acid, methyl red and iodine were studied and photographs taken. It was found that the seeds contain abundant starch grains. The petroleum extract was found to be the largest, constituting about 92 % and water extract only 6.33%. The extracts were found to contain carbohydrates, phytosterols, proteins, phenolic compounds and sapoins. The chloroform extract was found to give the maximum number of spots in TLC.

CP$_{23}$ A preliminary pharmacognostic study of *Aerva lanata* Linn.

R.Mallikaeswari, Manoharan, K.Senthil Babu*.

Division of Pharmacognosy, K.M.College of Pharmacy, Uthangudi, Madurai-625 107.

The plant *Aerva Lanata* family Amaranthaceae is an erect herb found throughout India as a common weed in field and waste places. The present study comprises of pharmacognostical and phytochemical details. Macroscopy and microscopical studies of entire plant was carried out. Physicochemical evaluation was carried out to determine the LOD, Total ash, water soluble ash, Acid insoluble ash and extractive values using alcohol and water as solvents. The plant was examined for its heavy metal

concentration such as lead, mercury and arsenic. It was confirmed that the plant was free from all these heavy metals.

Phytochemical study was carried out on ethanolic extract of the entire plant. The yield was about 6% w/w. It was found that alkaloids, flavonoid glycoside, phytosterols, phenolic compounds, tannins, sugars and proteins were present as phyto constituents.

CP 24 *Premna integrifolia* : phytochemical studies on root extract and it's anti-inflammatory action

S.M. Verma, Ruchir Jhingran, Ritu Gupta, Soni Kumari, Amrisha

Department of Pharmaceutical Sciences, BIT, Mesra, Ranchi – 835 215.

Premna integrifolia is a shrub or small tree widely distributed in India, belonging to the family Verbenaceae. It has been used traditionally for cure of several diseases like bronchitis, diabetes, neuralgia and rheumatism. It has been found to have hypoglycaemic, hypotensive, laxative and antibacterial action. The present work was undertaken to do phytochemical screening, characterization and study the anti-inflammatory activity of the root of P. integrifolia.

The dried roots of the plant after suitable size reduction and microscopical examination, were subjected to extraction of the active constituents using methanol and chloroform in soxhlet apparatus. Phytochemical screening of both the extract has shown the presence of alkaloids, flavonoids, tannins and terpenoids. TLC using typical solvent systems and adsorbent silica-GF verfied the presence of alkaloids and flavonoids in the methanolic extract. The R_1 values for both the constituent were found. The plates were observed under U.V. lamp at 254 nm and 365 nm. The maximum absorbance (I_{max}) was found to be 296 nm. PTLC was also carried out to quantify the active constituents. The methanolic extract was used for anti-inflammatory activity in male albino rats weighing between 125-165 gm. The method involves carrageenan induced rat paw oedema method using plythesmograph working on mercury displacement method. The methanolic extract produced marked anti-inflammatory activity at the selected dose level on the carragennan-induced animals. Phenyl butzone was taken as a standard drug. The percent inhibition of oedema was found to be 9.09% and 15.38% after 3 hours and 6 hours respectively.

The methanolic extract of the root of *Premna integrifolia* having the flavonoidal and alkaloidal constituents holds good potential as anti-inflammatory agent.

CP 25 Pharmacognostical, preliminary phytochemical and pharmacological studies on the tubers of *Cyperus rotundus* Linn.

S. Hemalatha, S. Hurmathunnissa, N. Anitha, Elavarasi*, Nagavalli, T. Vetrichelvan

Adhiparasakthi College of Pharmacy, Melmaruvathur.

The plant *Cyperus rotundus* belonging to the Family Cyperaceae is known as korikilangu in Tamil. The plant is distributed through out India as weed in wastelands from sealevel to 1800m. The plant has many Folk uses. It is used in epilepsy, loss of memory, blood diseases, fever, Helminthiasis, dysentry, vomiting and general ability.

The present investigation was aimed to pharmacognostical, preliminary phytochemical and pharmacological studies on the Tubers of cyperus rotundus.

Pharmacognostical studies on the Tubers were performed. Preliminary phytochemical screening in various extracts revealed the prescence of alkaloids, flavanoids, volatile oils, amino acids saponins, tannins, carbohydrates and mucilage.The extractive values of each extract were calculated.

Antioxidant activity was carried out by TLC method (Aluminium backed silicagel plate) using petroleum ether extract, chloroform extract, Acetone extract, methanol extract and aqueous extract against standard. Ethyl acetate and petroleum ether were used as solvent system in the ratio of 1:1

The chlorofom extract, methanol extract and Acetone extract shows the prescense of Antioxidant activity, which the inhibited area shows spots against purple background when sprayed with 1% DPPH in 2% methanol.

The alcoholic and aqueous extracts of the plant were subjected to Anticonvulsant activity. The duration of tonic hind limb extension in rats with alcoholic and aqueous extracts are studied which shows highly significant Anticonvulsant activity in rats. The extract in the doses of 100mg/kg significantly reduced the duration of hind limb extension when compared to standard drug.

CP 26 Antioxidant and antimutagenic activity of grape seed proanthocyanidins

H.N.Shivaprasad*, K.Girija, Salma Khanam & S.Mohan

Department of Pharmacognosy, P.E.S College of Pharmacy, Bangalore 560050

Recently there has been an increased interest in the food industry and preventive medicine in the development of natural antioxidants and antimutagens from plant material. There is a growing interest in the potential health benefits of Proanthocyanidins including its antioxidant and antimutagenic properties.

In our study, Grape seeds were selected and extracted with methanol. Extract was tested for their total polyphenolic content using Folin-ciocalteu's method. Further the extract was subjected to UV analysis to quantify Proanthocyanidin content.

The extract was studied for the antioxidant potential by in-vitro DPPH method. Ascorbic acid was used as a standard. Grape seed Proanthocyanidins showed potent antioxidant activity when compared to ascorbic acid.

Further, grape seed proanthocyanidin extract [100mg/kg for 7 days orally] was screened for antimutagenic activity against cyclophosphamide-induced mutation using mouse bone marrow micronucleus test. Micronucleus assay is an almost complete system for measuring various genetic mishaps during mutagenesis. Since cyclophosphamide takes not less than 10 hrs to induce mutagenic effect, bone marrow samples were collected after 24, 48 and 72 hrs of cyclophosphamide administration [I.P 50mg/kg]. Slides were prepared and stained for scoring polychromatic erythrocytes [PCEs] and normochromatic erythrocytes [NCEs] and incidence of micronuclei in these cells. An individual not otherwise involved in the study randomized the slides. Grape seed extract treated animals have shown a significantly decreased number of micronuclei both in PCEs and NCEs. The cyclophosphamide induced decrease PCEs/NCEs ratio, which is indicative of mitotic suppression, was normalized in treated groups. These results indicate significant protection against cyclophosphamide induced mutagenic effect of the grape seed extract at all the time interval tested.

CP$_{27}$ Isolation of amino acid from *Adenia hondala* plant

S. Kambhoja*, K.R. Keshava Murthy[1]

* Krupanidhi College of Pharmacy, Bangalore-34.

1. Regional Research Centre (Ayur), Jayanagar, Bangalore

Adenia hondala (Gaertner) de Wilde is a tendril climber with pachypodous base family Passifloraceae. In Ayurveda it is known as vidari.

The tuber was collected and washed with water to remove earthy matter and chopped into pieces and dried for three days under sun and powdered. It was extracted with different solvents acetone, ethanol, methanol and ethyl acetate by maceration process. Preliminary phytochemical analysis was carried out for different extracts. It was found that amino acids and reducing sugar were present in the extracts. Paper chromatographic studies was carried out using standard amino acids manufactured by lobo chemies, Bombay using a) Methanol : water, b) n-butanol : acetic acid : water and spraying reagent 4% ninhydrine in n-butanol. Rf values were calculated and it was found that the Rf values of threonine and methanol extract was same with single spot. The extract was concentrated and evaporated on water both gives white amorphous powder similar to that of standard amino acid threonine.

CP$_{28}$ Heptoprotective activity of *Momordica charantia* Linn against CCl_4 induced heptotoxicity in rats

Sridevi Nayak. M*. Gopkumar P. and V. Swamy

S.A.C. College of Pharmacy, AIMS Campus, B.G.Nagar 571448, Karnataka, INDIA

Momordica charantia Linn (cucurbitaceae) is the plant selected for evaluation of hepatoprotective activity against CCl_4 induced liver toxicity. In the study Momordica charantia plant powder is subjected for successive extraction with solvents like Pet. ether, benzene, chloroform, ethanol using soxhelation process. All the extracts were screened for hepatoprotective activity in male waster rats. The extracts when administered to mice as a single i.p. dose of 2000mg/kg was found to be nontoxic. Hepatoprotective activity was evaluated by measuring the reduction in elevated serum levels due to CCl_4 intoxication of enzymes like GOT, GPT, ALP, total bilirubin and assessment of liver section for recovery for degeneration, necrotic changes.

Between different extracts chloroform and ethanolic extract exhibited significant hepatoprotective activity at 200mg/kg body weight, which was comparable to the activity exhibited by the reference standard, Silymarin in CCl_4 induced hepatotoxicity model. Charantin, steroidal saponin is a main component isolated from the chloroform, and ethanolic extracts, along with alkaloids and glycosides.

CP$_{29}$ Anti-anaemic activity of shoots of *Triticum asetivum* Linn.

Basavaraj Hatapakki* , Lalit Rane and Suresh.H.M.

KLES's College of Pharmacy, J T College Campus, P.O. Box. 23, Gadag 582 101. Karnataka

Triticum aestivum Linn is widely cultivated throughout the world as a crop. The shoots of *Triticum aestivum* Linn are commonly called as wheat grass. The shoots are rich source of proteins, amino acids, vitamins, minerals and chlorophyll. The shoots

are useful in increasing blood cell count, lowers blood pressure and wheat grass juice stimulates the thyroid gland. It has been documented in treatment of Peptic ulcer, ulcerative colitis, constipation, diarrhoea. However anti-ulcer activity of the drugs has not been investigated.

In the present study, the fresh shoots (8 and 15 days old) were supplied by Rare Food Cultivators (Mushroom Division, Belgaum). The 8 days old shoots were extracted with water and alcohol by cold maceration for 15 days. The 15 days old shoots were also extracted with water for 15 days. Phytochemical investigation of 8 days and 15 days old shoots revealed the presence of vitamins (Thiamine, Nicotanamide, Pyridoxine, Ascorbic acid, a-Tocopherol), Free amino acids, Proteins and Chlorophyll. The above mentioned principles were identified by Chromatography and estimated by spectrophotometric methods.

All the three extracts were screened for anti-anaemic activity on male albino rats (Phenyl hydrazine induced anaemia) by comparison with the Normal group & positive control group. The study included the haematological parameters (RBC count, Hb count); Biochemical parameters (estimation of Cathepsin activity in spleen) and Bone marrow study (normoblast count and reticulocyte count). The aqueous extracts of 8 days old shoots showed most prominent activity while the other two extracts also exhibited statistically significant anti-anaemic activity.

CP 30 Investigation on medicinal plant seed oils for their physico-chemical characters

S.S. Jalalpure[1]*, K.R. Alagwadi[1], M.B. Patil[1], S.M. Patil[1], L.N. Shetty[1] and F.V. Manvi[1]

[1]Dept of Pharmacognosy, KLES's College of Pharmacy, Nehru Nagar, Belgaum - 10

To investigate Mucuna pruriens seed powder and seed oil for their physicochemical characters.

Mucuna pruriens investigated the chemical composition, nutritional characteristics and qualitative values of proteins isolated lecithin from seeds and was identified by TLC on silica gel by using chloroform / Methanol/ water system and by determining the phosphorus, nitrogen ratio. In the present study seed powder was subjected to extractive value loss on drying, Ash values, Total ash, acid insoluble ash, florescent analysis, total active principles, total microbial content and for seed oil, TLC profile, Extraction of oil, Total volatile matter, specific gravity, refractive index, acid value, Saponification value, Hydroxyl value and Total microbial count were investigated.

After performing all the physicochemical parameters for the seed powder and seed oil the results showed comparable readings when compared to I.P. standards.

CP 32 Pharmacognostic and phytochemical investigations on the aerial parts of *Cyphostemma setosum* (Roxb.) Alston

Nartunai G*, Jayaraman P. Reddy P.M.K. Rajendran.N.N.

59, Rainbow Nagar, II Cross Street, Pondicherry 605 011

The plant *Cyphostemma setosum* (Roxb.) Alston, Fam: Vitaceae commonly known as Pullabachali, is widely spread in India. Traditionally the ground leaves of the plant is used internally for stomach ache. Literature survey indicates that the Pharmacological properties of ethanol: water(1:1) extract of aerial parts of the plant have been well documented. However no reports are available on its pharmacognostic and phytochemical properties and so in the present study the same investigated.

The pharmacognostical study of leaves was carried out by microscopical analysis. The physical constants like ash values and extractive values of the aerial part of the plants were also examined. The ethanol: water extract of the aerial parts were subjected to phytochemical screening by quantitative organic analysis and HPTLC analysis in chlotoform:methanol solvent system. UV spectroscopic data of the fraction obtained from chromatography was also studied.

The unbranched thick shaggy type of glandular trichomes and the undifferentiated lamina into palisade and spongy parenchyma are the important pharmacognostic characteristics which will help to differentiate the plant from other species of the same genus Cissus. The values of total ash, acid insoluble ash, water soluble ash, and sulphated ash of aerial parts are 17%, 4.5%, 4% and 24% respectively which are specific to the plant for identification. The ethanol and water-soluble extractive values were 8% and 10% respectively, which indicated the nature of constituents present. Qualitative organic analysis revealed the presence of tannins, flavonoids and phenols. The UV spectra of the fraction obtained from column chromatography showed a peak at 272 nm, which may be due to flavonoids. The HPTLC pattern of ethanol:water(1:1) extract of aerial parts showed 6 peaks at 0.05,0.49,0.62,0.74,0.86 and 0.95. The peak at 0.62 appeared predominant which on subjecting to ammonia vapours produced distinct yellow colour, possibly due to flavonoid as supported by quantitative organic analysis.

The pharmacognostic studies of the plant Cyphostemma setosum(Roxb.)Alston will help to identify the plant and the phytochemical studies throw more light on exploration of active constituents for varied pharmacological activities.

CP 33 Pharmacognostical & phytochemical investigations on the roots of *Butea monosperma* (Lam.) Taub.

P.V. Laghate* & N.D. Grampurohit

C.U. Shah College of Pharmacy, S.N.D.T. Women's University, Santacruz (W), Mumbai 400 049.

Butea monosperma (Lam.) Taub (Synonym: Butea frondosa Koen. Ex Roxb.), belonging to the family Fabaceae, is a commonly growing tree throughout the mountainous regions of India. The plant is commonly known as Palash or Palasha or Khakara. Ayurvedic literature mentions the medicinal uses of various parts of the plant such as the leaves, roots, bark and gum. The literature survey indicated that the roots (Khakara mula) have anti-inflammatory activity and are useful in eye diseases but very little work has been carried out pertaining to their standardization and phytochemical investigations. Hence, this research paper describes pharmacognostical and phytochemical evaluation of the roots.

The authenticated roots of *B. monosperma* were studied microscopically by taking T.S. and powder characteristics and their photomicrographs were recorded. Physicochemical parameters viz. water and alchohol soluble extractives, total ash and acid insoluble ash were determined according to pharmacopoeial procedures. The roots were extracted in a Soxhlet extractor successively with pet-ether (60°-80°c), chloroform, ethyl acetate, methanol and water. The extracts were screened qualitatively for phytoconstituents such as alkaloids, anthraquinone glycosides, tannins and phenolic compounds, sugars, saponins, flavonoids and resins. The successive extracts were studied by Thin Layer Chromatography to confirm the chemical nature of phytoconstitiuents.

- The pharmacognostical investigations showed the presence of cork, cortex, secondary phloem and secondary xylem region with abundance of starch grains.
- Phytochemical screening of the successive extracts revealed the presence of lipids, carbohydrates, resins, tannins, steroids, other phenolic compounds and gums.
- TLC studies with spray reagents revealed the presence of 6 compounds of steroidal nature and 6 compounds of triterpenoid and saponin nature
- Microscopical examination of the roots showed the presence of abundance of starch grains and pigement cells which can be used as a tool for the identification of the roots.
- The roots show the presence of phytoconstitiuents such as lipids, carbohydrates, tannins, steroids, other phenolic compounds and gums.
- TLC studies revealed the presence of 6 compounds, which were of steroidal nature and 6 compounds of triterpenoid and saponin nature.

CP 34 Investigation into the antidiabetic effect of *Brassica oleracea* L. (Gongylodes)

Syed M. Mansoor* and Rema Razdan

Visveswarapura Institute of Pharmaceutical Sciences, 24 Main Road, 25 Cross Road, KIMS Building, BSK 2 Stage, Bangalore 560 070

Brassica oleracea L (gongylodes) commonly known as knol-khol is routinely used as a vegetable throughout India. Knol-khol juice is widely prescribed in naturopathy for antidiabetic therapy. A study was conducted to evaluate the possible antihyperglycemic activity of different extracts of Brassica oleracea (gonglylodes) in alloxan induced diabetic rats, to evaluate oral glucose tolerance test (GTT) on glucose fed hyperglycemia in rats and possible hypoglycemic effect in normal rats. Diabetes was induced in 16hour fasted female Sprague - Dawley rats with alloxan monohydrate (100mg/kg p.o.). After 72 hours, rats with marked hyperglycemia (fasting blood glucose > 250 mg/dl) were selected and used for the study. Serum glucose was estimated by glucose oxidase method. The aqueous extract (1.8g/kg,p.o.) and petroleum ether extract (30mg/kg,p.o.) produced significant reduction in serum glucose levels, maximum of 22% at 2hour and 41% at 4hour respectively. This was comparable with the effect of glibenclamide (48% reduction at 4hour). GTT was studied after oral administration of glucose 10g/kg. The aqueous extract and petroleum ether extract produced significant reduction in serum glucose levels, maximum of 112% at 30minutes and 65% at 30minutes respectively. Glibenclamide produced a maximum reduction of 102% at 30minutes. Freeze-dried juice (5g/kg,p.o.) showed an increase in serum glucose levels in diabetic and glucose fed normal rats. In normal rats, the aqueous extract and the petroleum ether extract did not reduce serum glucose levels. Thus the aqueous extract and the petroleum ether extract of *Brassica oleracea* exhibited significant antihyperglycemic activity in diabetic rats and in glucose fed normal rats. The freeze-dried juice exhibited hyperglycemic effect in diabetic and glucose fed normal rats. The extracts did not exhibit hypoglycemic effect.

CP 35 Study of hepatoprotective activity of aqueous extract of *Scoparia dulcis* L. against carbon tetrachloride induced pentobarbitone sleep time prolongation in rats

Rema Razdan, Praveen T.K., Amar Dev*

Dept. of Pharmacology, Visveswarapura Institute of Pharmaceutical Sciences, 24 Main Road, KIMS Building, BSK 2 Stage, Bangalore 560 070

Most of the xenobiotics cause hepatotoxicity by getting metabolized to active metabolites through cytochrome P450 (CYPs). These toxic metabolites cause damage to different cellular organelles, including CYPs. Hence drugs having potential ability to protect the CYPs from the damage caused by the toxic metabolites can also act as potential hepatoprotectives.

An attempt has been made to study the CYPs protective ability of aqueous extract of Scoparia dulcis L. against CCl_4 induced pentobarbitone sleep time prolongation in rats.

The results obtained from the above study suggest that rats treated with CCl_4 have shown significant increase in pentobarbitone sleep time 166.83 ± 5.1 minutes (mean ± SEM, n = 6) when compared to the normal control sleep time 80.3 ± 1.3 minutes (mean ± SEM, n = 18). Rats treated with aqueous extract of *Scoparia dulcis* L. (0.5 g / kg, p.o.) significantly prevented the CCl_4 induced prolongation of sleep time. 128.0 ± 7.2 minutes (mean ± SEM, n = 6). In conclusion the results obtained from the above study suggest that aqueous extract of *Scoparia dulcis* L. *possess* the CYPs protection ability and hence antihepatotoxic activity.

CP 36 Effect of saponins of *Acorus calamus* Linn on serum lipid profile and fecal cholesterol in rats

Snehalatha P'., and Mengi S.

C.U. Shah College of Pharmacy, SNDT Women's University, Juhu, Santacruz (W), Mumbai 400 049

Hyperlipidemia is acknowledged as a major risk factor for coronary heart diseases. Present treatment has limitations with respect to side effects. The present era sees the use of the medicinal plants being evaluated for a number of diseases and disorders. The present study deals with the plant *Acorus calamus* in the treatment of hyperlipidemia. Earlier studies conducted have revealed hydroalcoholic extract to demonstrate hypolipidemic activity. Since phytochemical studies indicated preponderance of saponins, they were evaluated at a dose range of 10-40 mg/kg for hypolipidemic activity. The effect of saponins on serum lipids and faecal cholesterol in rats fed with an atherogenic diet was investigated.

Saponins were extracted from the hydroalcoholic extract of the rhizomes of *Acorus calamus*. The extracts at doses of 10 mg/kg, 20 mg/kg and 40 mg/kg and the reference drug Gemfibrozil 30 mg/kg were suspended in 0.5% Na CMC and were administered orally to rats. Collected faeces were homogenised, extracted ($CHCl_3$:CH_3OH) and faecal cholesterol was estimated.

Results indicated a dose dependent reduction in the serum cholesterol and triglycerides and increase in the HDL-cholesterol levels with saponins. However, saponins failed to bring cholesterol and triglycerides levels back to the base line value. Standard drug Gemfibrozil 30 mg/kg demonstrated a lipid profile similar to that of saponins. The faecal cholesterol levels were found to be significantly increased with saponins thus suggesting interference with intestinal absorption as observed by earlier workers.

CP 37 Evaluation of anti-urolithiatic activity of *Aerva lanata* in *calculi producing* diet induced urolithiasis

H.C. Satheesh* and Rema Razdan

Institute of Chemical Technology, University of Mumbai, Matunga (East), Mumbai 400 019

Department Pharmacology, Visveswarapura Institute of Pharmaceutical Sciences, 24, Main Road, 25 Cross Road, KIMS Building, BSK 2 Stage, Bangalore 560 070

Aerva lanata juss (Family: Amaranthaceae) also known as Pashanabedha is used traditionally in ayurvedha in the south India for treatment of renal calculi. The present study was conducted to assess the efficacy of the ethanolic extract of the whole plant of *Aerva lanata* for its antiurolithiatic activity in 3% w/w glycolic acid induced urolithiasis in male Sprague Dawely rats.

The rats were divided into five groups of six animals each.

Group 1: Received the commercial diet and served as control.

Group 2: Were administered a calculi-producing diet (CPD: commercial diet mixed with 3% w/w glycolic acid) for 35 days.

Group 3 : Were administered CPD and the ethanolic extract of *Aerva lanata* (300mg/kg / day,p.o.) for 35 days to observe for the prophylactic effect.

Group 4:Were administered CPD for the same duration, and the ethanolic extract of Aerva lanata (300mg/kg / day,p.o.) was administered orally during last 10 days to observe for the curative effect.

Group 5: Received commercial diet and were administered the ethanolic extract of Aerva lanata (300mg/kg /day,p.o.) for 35 days

The treatment with ethanolic extract of whole plant of Aerva lanata (300mg/kg/day,p.o.) significantly did not show a reduction of urinary calcium, oxalate and phosphorous levels. The histopathological study of kidney did not show any significant reduction in calcium oxalate deposits in prophylactic and in curative group when compared to CPD fed group.

Thus ethanolic extract of whole plants of *Aerva lanata* at a dose of 300mg/kg/day,p.o. when administered for 35 days did not show a protective effect in the CPD induced urolithiasis model of rats.

CP 38 Antidiarrhoeal activity of *Ablesulmos esculante* Linn in Albino rats

Chandrashekhar.V.M*., Habbu P.V., Muchandi.I.S., Srinivas.Y and K.Purushotham Rao[1]

Hanagal Shri Kumareshwara College of Pharmacy. Bagalkot –587101. (Karnataka)

[1]H.K.E'S College of Pharmacy ,Gulbarga-585101.(Karnataka)

The plant *Abelmocshus esculentus* Linn (Malvaceae) as been used in traditional system medicine for treatment of gonorrhea, the bland mucilage of fruit is often beneficial for the treatment of dysentery and diarrhoea . The vapor form of hot decoction is used as inhalation in irritable throat. The present study aims to evaluate the suspensions of ethanolic extract, petroleum ether extract and aqueous extract of fruits of Abelmoschus esculentus for its antidiarrhoeal activity by gastrointestinal motility test, castor oil induced diarrhoea and Prostaglandin E_2 induced enteropooling in rats. The study revealed that suspension of ethanolic extract showed significant decrease in propulsion of charcoal meal through GIT ($p<0.001$), significantly reduced the diarrhoeal episodes ($p<0.001$) and inhibited prostaglandinE2 induced enteropooling ($p>0.001$). The suspensions of aqueous extract and petroleum ether did not show significant antidiarrhoeal activity.

CP 39 Wound healing activity of *Sebastiania chamaelea* Muell - arg

Kandepu Nischal*, Ebenezer devadhas, T. Subburaj, K. Elango and B.Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund.

Sebastiania chamaelea belongs to the family Euphorbiacea a tribal medicinal plant used by the kurumba tribals of Western Ghats for the treatment of wound healing. A thorough literature survey showed that much work was not done on the plant in this direction, hence a systematic study was conducted via Incision, Excision and Burn wound model at a dose level of 1%, 5% w/w of methanolic extract in ointment base. Povidone iodine was used as positive control. The results showed that at both concentration wound closure was about 87.1% and 88.6% after 8th day. On 14th day a complete healing took place in Excision wound model. In Burn wound model the percentage of closure was 68% and 69.83% respectively at 1% and 5% w/w dose levels, where as the positive control silver Sulphadiazine was 55.5% on 8th day. On 16th day it was found that total wound was healed. In the case of incision model a significant result was obtained and the tensile strength was also showed significant increase at 5% w/w concentration.

CP 40 Anti bacterial and antifungal activity of marine sponge *Sigmadocia Fibulata*

Ravi, R*, Binokingsly. R, Sathesh Kumar .S Hemalatha. R, Venkat Narayanan. R Suriya Prakash. T.N.K.

SB College of Pharmacy, Anaikuttam, Sivakasi 626 130, Tamilnadu

Ocean are wealth of organism with Pharmaceutical value. Today all of the Pharmaceuticals derived from natural sources have been obtained from terrestrial organism. How ever discoveries in the past 25 years indicate that our oceans may provide the Pharmaceuticals for the next millennium. Drug discovery efforts along the lines of that marine invertebrates such as sponges are more prolific source of new anti - cancer, anti-viral and anti-inflammatory agents than any group of terrestrial organism

Study of marine natural products have already made some significant contributions towards the discovery of new Pharmaceutical agents. Over the past 20 years their research programs have provided a spectacular array of novel compounds, many of which posses useful biological or Pharmaceutical properties.

The invitro antibacterial and antifungal activity of extracts of marine sponge *'Sigmadocia Fibulata'* (Family Adocidae) have been investigated against *S. Pyogens, S. Typhi, Pseudomonas* and *C. albicans*. The chloroform and methanol extracts showed high degree of activity against all test organism except C. albicans. The extracts doesn't show any growth of inhibition against test fungi C. albicans. The inhibitory effects of extracts are very close and identical in magnitude and are comparable with that of standard drugs used.

CP 41 Preliminary studies of anti-inflammatory effects of the root of *Asparagus racemosus Willd*

N. Venkatesan*, R. Vadivu, J. Britto Perianayagan U. F. Askar Ali, A. Gunakkundru, Sivakumar.

Faculty of Pharmaceutical Science Guru Jambhushwar University, Hisar - 125001

K. P. College of Pharmacy, Tiruvannamalai 606 603.

The plant *Asparagus racemosus Willd.* is well known for its pharmacological activities. The plant contains carbohydrates steroids and saponins. The herbal product of methanolic extract has been conceived and its effect on Carrageenan induced rat paw Oedema was studied in the preliminary screening experiment. Having obtained encouraging results in the above model we carried out the effects of the same combination in croton oil induced mouse ear oedema and cotton pettet granuloma models. Wister albino rats of (180-200gms) either sex were used in cotton pettet granuloma and albino mice (20-28gms) of either of the *Asparagus racemosus* was tested on croton oil induced mouse ear oedema and cottton pellet granuloma. The 200mg / Kg exhibited 85% inhibition in carrageenan induced paw oedema as against 71.21% shown by 10mg/Kg of indomethacin. In croton oil induced mouse ear the inhibition was found to be 85.05% and that of indomethacin 30.06% Effect of the extracted drug in cotton pellet induced granuloma formation is as good as that of indomethacin. 55% induction in the weight of the granuloma tissue on the cotton pellet was observed. The anti-inflammatory effect of the extract was compared with standard drug such as indomethacin both in sub acute experimental models of inflammation in albino mice and Wister rats.

CP 42 Evalution of pharmacognostic standards for root of *Asparagus racemosus willd*

N. Venkatesan*, R. Vadivu, J. Britto Perianayagam, R. Sankar, S. Murugesan, K. Padmanaban

Faculty of Pharmaceutical Science Guru Jambhushwar University Hisar 125 001
K. P. College of Pharmacy, Tiruvannamalai 606 603

The root of *Asparagus racemosus* Willd is most commonly known drug in traditional system of medicine. The medicated oil "Narayana taila" from this plant is used in Ayurveda & Siddha for nervous & rheumatic trouble. The present study was undertaken with an objective to establish pharmacognostic standards for *Asparagus racemosus* Willd. So, that authentic plant could be explored for its claim in traditional system of medicine.

The plant in a climber growing to 1-2m in length and roots are finger like and clustered. The root is used in indigenous system of medicines as glactogenic, antidiarrhoetic, antidysentric, antiseptic, aphrodisisc, antispasmodic and anti-inflammatory.

This study includes macro-microscopical characters and estimation of physiochemical values. From the studies it was concluded that *Asparagus racemosus* Willd is identified by microscopic characters of root specially the shape, size and fracture transverse section of root showed the presence of outer exodermis, middle cortex zone with raphides and mucilaginous cells, central vascular cylinder with exarch protoxylem and wide metaxylem points, endodermis and pith. Powder characters showed the presence of cortex with raphides, xylem vessels and exodermis. The physiochemical standards includes ash values (Total ash, acid insoluble ash and water soluble ash) and extractive values (alcohol soluble extractives and water soluble extractives. Total ash of the root of *Asparagus racemosus* Willd is 2-3 times more than that of acid insoluble ash and water soluble ash. Water soluble extractive value is higher than alcohol soluble extractive value.

CP 43 Pharmacognostic evaluation and anti microbial activity of *Tylophora indica* Merill

R. Mallikeswari, Sudha Keshavardini, E. Susithra*.

Division of Pharmacognosy, K.M.College of Pharmacy, Uthangudi, Madurai 625 107.

Tylophora indica Family Asclepiadaceae is a branching climber, an important plant used against various disorders in indigenous systems of medicine. In the present communication, the detailed pharmacognostical studies of the entire plant was carried out. Leaf constants such as Vein-islet number, Veinlet termination number and stomatal index were calculated.

Physico-chemical constants like LOD, Total ash, Acid insoluble ash, water soluble ash and Extractive values of the entire plant were carried out.

The whole plant was extracted for its phytochemical constituents. The menstrum used was 90% v/v alcohol. The method adopted was hot continuous percolation. A dark green waxy residue of about 9% w/w was obtained.

The extract was subjected to qualitative analysis for the presence of various phyto constituents. The study revealed that the plant has alkaloids, phytosterol, and sugars as its natural components.

The anti microbial activity of the ethanolic extract at various concentrations was studied against *Staphylococcus aureus* (gm +ve) using filter paper disc method. The standard used was an antibiotic Amikacin. It is concluded that the anti microbial

activity of alcoholic extract was gradually increased while increasing the concentration of extract against *Styphalococcus aureus*.

CP 44 Standardization of herbal medicines

K.S. Patil[1], Rajarajeshwari .N[1*], Suresh Babu A.R[1], S.C. Chaturvedi[2]

1) K.L..E.S's College of Pharmacy, Belgaum

2) Shri. G.S.I.T.S. Department of Pharmacy, Indore.

Herbal Medicines are becoming increasingly popular among consumers, the increasing demand for herbal medicines inevitably led to the issue of obtaining and maintaining their quality. As a result, there has been a tremendous quality consciousness for the herbs in countries like U.S.A., member countries of European Union, China and Australia etc. Unfortunately how ever, in our country, concept of quality did not get much attention. Hence, in this article an attempt has been made to Guide the main streams of standardization of herbal medicine.

Although herbal remedies have been used for centuries many of them without apparent serious damage to the user, they are not necessarily safe, and reports citing problems associated with their use are increasing. Hence, the standardization problem raised.

The Indian council of medical research (ICMR) has adopted a disease oriented strategy for validating the claims of efficacy of traditional herbal remedies, and have initiated clinical trials of such drugs in the areas of anal Fistula, bronchial asthma, viral Hepatitis, Urolithiasis, diabetes and filariasis.

The only centre established in the country by the ICMR for the purpose of formulation, standardization and maintaing quality of such drugs inducted in clinical trails in these areas is the ICMR centre for advanced research at the department of pharmaceutical sciences, Panjab University, CHANDIGHARH.

CP 45 Evaluation for anti-Inflammatory activity of total and fractionated extracts of *Vitex negundo*

Kulkarni R.RD., Virkar A.D.*D, Naik, S.Ry., D'Mello P.M.D

Department of Pharmacognosy and Phytochemistry, Department of Pharmacology, Principal K.M.Kundnani College of Pharmacy, Worli, Mumbai.

Vitex negundo Linn. (Nirgundi) is a common shrub growing throughout India. The plant is reported in Ayurveda to be effective against all types of inflammatory disorders like sinusitis, endometrits, colitis and the leaves are used in pain and oedema seen in arthritic patients.

The present project deals with investigations on anti-inflammatory activity of total and fractionated extracts of *V.negundo leaves*. The anti-inflammatory activity has been evaluated by Carageenan induced "Rat Paw Oedema Inhibition" method. On phytochemical evaluation, the hydroalcoholic extract of *V. negundo* leaves revealed the presence of flavanoids and irridoids.

This extract has demonstrated a significant anti-inflammatory activity by causing 69.08% inhibition in oedema at the third hour as compared to vehicle control. Diclofenac Sodium was used as positive control.

The residual extract remaining after fractionation with ethyl acetate exhibited a lower activity (41.73% inhibition) as compared to total extract; indicating a possible extraction of phytoconstituents in ethyl acetate.

CP 46 Evaluation of antimicrobial activity & phytochemical screening of *Luffa acutangula*

V. P. Chavan*, S. S. Patil*, C. S. Magdum, D.D. Chougule, S. A. Tamboli, K. A. Wadkar

A.B. College of Pharmacy, South Shivaji Nagar, Sangli 416 416 (M.S.)

Luffa acutangula is a climber belonging to the family Cucurbitaceae. The crude leaf juice of this plant is used in the villages of India for its property to extract worms from the infected wounds in animals & also for its use in treating the granular conjunctivitis in childrens.

The present research work is to evaluate the antimicrobial activity of the crude leaf juice, 20% aq. extract of the fresh leaves 20% aq. extract of the dried powdered leaves & 20% alcoholic extract of the dried powdered leaves of this plant. The extracts were also subjected for qualitative chemical analysis. The aq. extracts were obtained by using 10% chloroform water by maceration for seven days & the alcoholic extracts was obtained by Soxhlet extraction by using ethanol as solvent. The antimicrobial activity of the extracts were evaluated by "Disc diffusion method" against the Gram positive organisms like *Staphylococcus aureus* ATCC 3750, *Staphylococcus aureus* (coagulase positive) & Bacillus subtilus var. niger ATCC 937, *Candida albicans* ATCC 10231and Gram negative bacteria like *Pseudomonas aeruginosa, Proteus vulgaris, Escherichia coli, Salmonella typhi & Klebsiella pneumoniea.*

Amongst the tested microorganisms, the Gram positive bacteria i.e. *Staphylococcus aureus* (coagulase positive) Bacillus subtilus var. niger ATCC 9372 & Candida albicans ATCC 10231 were found to be

resistant to the crude leaf juice, the aq. & alcoholic extracts of the leaves but only *Staphylococcus aureus* ATCC 3750 was sensitive to all the extracts except crud leaf juice. Amongst the tested Gram negative bacteria, *Pseudomonas aerugenosa* was found to be sensitive to the crude leaf juice aq. extracts of fresh leaves & aqueous extracts of powdered dried leaves . *Proteus vulgaris* was found to be sensitive to both, the aq. extracts of the fresh leaves & aq. extracts of the powdered dried leaves. *Escherichia coli* alone was found to be inhibited by the aq. extracts of the fresh leaves.

The chemical qualitative analysis showed that 1) Aq. extract of fresh leaves contains triterpenoids, carbohydrates and alkaloids.2) Aq. extraxt ofpowdered dreid leaves contains triterpenoids, carbohydrates, alkaloids and flavonoids. 3) Alcoholic extract of the leaves contains triterpenoids, carbohydrates , alkaloids, flavonoids, saponins, sterols and tannins.

CP 47 Phytochemical investigation and pharmacological study of *Abutilon indicum* (Linn) for adaptogenic activity

Roshan S[1]*; Savadi R.V[2]; Hukkri V.I[2], Sanaullah S[1]

1. Luqman college of Pharmacy, Gulburga , Karanataka.
2. K.L.E's College of Pharmacy, Hubli, Karanataka.

Stress is a common problem and major health hazard of life. Stress is a particular response of the body by releasing certain harmones like caortisones and adrenaline. This leads to an increase in heart rate, blood pressure, anxiety, depression and hypertension. These anti stress agents resist against aversive stimuli and immunity to give protection against diseases, improve vigour vitality and longevity. The experimental work related to adaptogenic effect should not only explore the anti stress, but should also accounted in the improvement of defiance mechanism of host.

The ethanolic extract of *Abutilon indicum* (malvaceae) has been found to possess adaptogenic (anti stress) properties when tested against mice and rat at a dose 400 mg/kg. Body weight , swimming endurance test, anoxic tolerance test in mice and cold stress in rats model are selected for the evaluation of adaptogenic activity. The serum levels glucose, cholesterol, triglycerides BUN and also total WBC and differential count were measured.

The preliminary phyto chemical investigation of Ethanolic extract of *Abutilon indicum* shows presence of alkaloids, glycosides, phenolic compounds, sterols and amino acids. Significant increase in swimming time, anoxic tolerance test was determined by taking the appearance of convulsions as an end point for the increase in stress tolerance time. Cold stress increases the serum levels which influence the stimulation of hypothalamus to secrete ACTH. Abutilon indicum significantly decreases the serum levels of glucose triglycerides , cholesterol and BUN and also increased the count of WBCs.

In this study it was observed that Abutilon indicum manifests the stress effects it may be concluded that, Abutilon indicum significantly changes the serum levels of cholesterol, triglycerides, glucose and BUN, increases the swimming time and also increase the tolerance time, thereby justifying that Abutilon indicum has adaptogenic activity.

CP 48 Studies on the two species of *Berberidaceae* family in Nilgiris

Rakesh Kumar Garg*., Kalaskar Mohan G., Sagar Kumar Mishra., Duraiswamy B., Subburaj T., & Suresh B.,

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund.

Mahonia leschenaultii takeda & Berberis tinctoria lesch, are two species of Beriberidaceae family commonly distributed in Nilgiris and *Pulney* Hills of Western Ghats. The aqueous root paste of plants along with honey used as antimicrobial agent on the skin by the Nilgiri tribes, so microbial screening was carried out to confirm ethnobotonical claim. The root and root barks were air dried and mechanically powdered to obtain a course powder which have been subjected to successive extraction with chloroform and methanol using Soxhlet apparatus. The resulting extracts were subjected to antibacterial studies against Escherichia coli, *Pseudomonas aeruginosa, Staphylococcus aureus* and *Staphylococcus epidermitis* and antifungal studies against *Trichophytons lignorum* and *Candida crusei.* The extracts (20 mg/ml) were screened by cup plate method followed by serial dilution method using Ampicillin trihydrate (100 mg/ml) for antibacterial activity and Amphotericin B (100mg/ml) for antifungal activity as standard drugs. The extracts were showing good activity against all bacterial strains, with relatively better activity against Staphylococcus aureus. The antifungai activity was relatively less when compared with antibacterial activity.

CP 49 Pharmacognostical, preliminary phytochemical and comparative antibacterial studies on *Euphorbia rothiana* Spreng

K.Dhanabal*,Nilani.T.Tharan #, S.Mohan, Abhay Dharamsi, B.Dhandabani, A.G.Esaithamizh, and K.Geetha.

* K.M.C.H College of pharmacy, Kovai-Estate, Coimbatore-35.

P.S.G. College of Pharmacy, Peelamedu. Coimbatore.

Euphorbia rothiana (F:Euphorbiaceae) is a sub shrub growing in the Hills of Decan peninsular India. It is used to treat inflammative acne vulgaris by local trible peoples of Nilgri hills. The literature survey revealed that this plant has many medicinal values including Hypotensive, anthelmintic and Anti fungal activity. Even though it is known for it's anti inflammative acne vulgaris treatment no scientific investigations were conducted for its antibacterial activity hence this study has been conducted to evaluate the antibacterial activity of the plant.

The phamacognostical studies include macroscopical and microscopical studies of leaf, stem and root. The petroleum ether (60-80°C) chloroform, Acetone, Alcohol and aqueous extracts of leaf, stem and root are separately obtained by simple maceration method. All the 15 crude extract obtained was subjected to qualitative phytochemical analysis by using different reagents. The antibacterial activity of all crude extracts of *E.rothiana* is evaluated by cup plate method using some gram +ve and gram –ve bacterias such as *K. aerogenosa* (NCIM-2239) *E.Coli* (NCIM-2065). *P. Vulgaris* (NCIM –2027) *B.Subtilis* (NCIM-2063), *Staphy epidermis* (NCIM-2493) *Staphy aureus* (NCIM – 2079).

The microscopical study reveals the presence of flavanoidal constituents in the epidermal cells of the stem.The phytochemical tests reveal the presence of steroids,Alkaloids (only in leaf-chloroform and Alcoholic extracts), Glycosides, phenolic compounds and flavanoids in leaf, stem and root extract.Among the all extracts only Alcoholic and Aqueous extracts of leaf, stem and root shows the significant activity in that alcoholic extract of leaf shows potent antibacterial activity against tested micro organisms.

From the result obtained it can be revealed that the presence of phenolic compounds and flavanoids in the Alcoholic and Aqueous extracts might be responsible for the antibacterial activity. And our study confirms the Ethinomedical use of the plant.

CP 50 Phytochemical and pharmacological studies on bark of *Symplocos macrophylla* Wall ex. A. DC.

S. Kambhoja*, K.R.Keshava Murthy[1]

* Krupanidhi College of Pharmacy, Bangalore, Don Bosco Institute of Biosciences, Bangalore

Symplocos macrophylla wall ex. A.DC. bark belongs to the family: Symplocaceae. In Ayurveda it is known as Lodhra. The bark was collected and dried for four days under sun and powdered. It was extracted with different solvents ethanol, methanol and ethyl acetate by soxhlet hot extraction process. Preliminary phytochemical analysis was carried out for different extracts. It was found that saponin glycosides and carbohydrate were present in the extracts. Thin layer chromatography studies were carried out using Methanol: Chloroform and Methanol: Ethyl acetate. Spraying reagents a) 5% Alcoholic sulphuric acid, b) 1% Vanillin in alcohol. Rf values were calculated for the different spots. Extracts were screened for analgesic activity by Eddy's hot plate analgesiometsr using analgin as standard drug. The methanolic and ethyl acetate extracts has shown significant analgesic activity when compared to that of control

CP 51 *Coleus forskohlii* tissue culture – the effect of growth hormone on micropropagation.

Rajamma.A.J[*1]., Shashidhara.S[1]., Rajashekharan[2]

1. Dept. of Pharmacognosy, Govt. College of Pharmacy, Bangalore-27
2. Indian institute of Horticulture research, Hesaragatta, Bangalore-89.

Coleus forskohlii. Briq. (fam.lamiaceae) is an important plant in Indian ayurvedic medicine. Roots are rich in labdane diterpinoid forskolin (coleonol) and other diterpinoids such as coleonol and its related compounds, barbatusin and cyclobarbatusin. Invitro biological activity suggests that plant is having significant lowering of blood pressure and intraocular pressure, and also anti-inflammatory activity. The requirement of this plant for drug development indicates the need for sustained supply of root material in quantities that would threaten the survival of the species in nature. Hence this work was undertaken to study the effect of different hormones needed for its micropropagation.

Micropopogation was initiated from both leaf and nodal explants on MS media supplemented with different combination of growth hormones. Inoculation of leaf explant after sterilization on media supplemented with Kn, NAA + BAP, NAA + Kn and Kn + BAP +NAA in different concentrations produced callus on the cut edges of leaf explants with in 8-9 days and shoots were produced from this callus in another 10-12 days. Similarly nodal explants were also inoculated on MS media supplemented with Kn, NAA + BAP, NAA + Kn and Kn + BAP +NAA in different concentrations and direct generation of multiples of shoots with in 15- 20 days. Cultures were incubated at 25± 2°C under full light conditions. Sub culturing on same media and also on basal media produced multiplets of shoots.

Comparative studies of the explants indicated that both leaf and nodal explants were equally good for producing multiplets of shoots. Among the different combinations of growth hormones tested, BAP + Kn + NAA was found to be superior for the purpose of micropropagation

MS-murashige & skoog, NAA-a-Naphthalene acetic acid, BAP – Benzyl amino purine, Kn-Kinetin

CP 52 Free radical scavenging activity of some ethnobotanicals and Its comparison

N.H.Indurwade*, K.R.Biyani, S.P.Pakhale, V.V.Redasani, Rajendra Khade

S N Institute of Pharmacy, Pusad 445 204 (MS)

Cancer is one of the leading diseases in the developed as well as developing countries. Preventing oxidative damage is the simple and effective way of preventing cancer. To determine the Free Radical Scavenging activity, a method based on reduction of methanolic solution of colored free radical DPPH was used. The decrease in absorbance of DPPH is proportional to concentration of free radical scavenger added to DPPH reagent solution. The study shows that aqueous extract of *Terninalia chebula* shows marked inhibition as compared to *Citrus limonie, Vitex negundu, Eclipta alba, Ficus bengalensis*. Compare to the Ascorbic acid ($EC_{50\,\%}$ = 0.646 mg), *Terminalia chebula* shows 50 % inhibition at 0.88 mg. The results revealed that the antioxidant action is attributed to the free radical scavenging activity of the extracts may also participate in the natural defense mechanism of cancer.

CP 53 Estimation of flavonoid content and 1- DPPH scavenging activity of herbal extracts

C. Vijaya[a*], M. Ramanathan[a], T. Subburaju[b] and B. Suresh[a]

a. Department of Pharmacology

b. Department of Pharmacognosy, J. S. S. College of Pharmacy, Ooty- 643 001

* Presenting author

Flavonoids, with antioxidant activity, are one of the major phytoconstituents of the selected plant drugs, Aegle marmelos leaves, Medicago sativa aerial parts and Momordica charantia ripe fruits. In this study, 50 % ethanolic extracts of the drugs were standardized to their flavonoid content and were evaluated for their antioxidant property. The quantitative determination of flavonoids was done by aluminium chloride colorimetric method taking rutin as the flavoniod standard. The results showed a higher flavonoid content in Aegle marmelos leaf extract. The antioxidant activity of the extracts was measured by in vitro 1- diphenyl picryl hydrazyl (1- DPPH) radical scavenging assay and expressed as IC_{50} values (the concentration required to scavenge 1-DPPH radical by 50%). Aegle marmelos leaf extract was found to have the highest antioxidant activity as indicated by the low IC_{50} value. A linear correlation (r= 0.9535) between flavonoid content and antioxidant activity was noted. The study confirms the free radical scavenging potential of flavonoids.

CP 54 Anti-inflammatory activity of some traditionally used plants in Melghat region

Indurwade N.H., Biyani K.R., Jaju S.B.* Samdariya N.S.

S.N. Institute of Pharmacy, Pusad, Dist. Yavatmal

NSAIDs used to treat inflammatory disorders are often associated with various side effects like gastritis, intolerance, ulcers and allergic reactions. Chronic users of NSAIDs are three times more prone to serious gastrointestinal problem as compared to non-users.

In an attempt to investigate some herbs to treat inflammatory disorder, two traditionally used plants in Melghat region viz. *Euphorbia granulata* Forsk (alcoholic extract) and *Phyllanthus viragatus* (alcoholic extract) belonging to family Euphorbiaceae were tested for anti-inflammatory activity by rat paw oedema method in albino rats.

Significant inhibition of edema was found for both the plants i.e. 43.75% and 68.75% respectively, 3hrs after Carrageenan injection when compared to control. Findings obtained supported the traditional use of plants.

In future the formulation of the plant extract in dosage form may be an other area of research.

CP 55 Diuretic activity of the extracts of *Cordia cichotoma forst.f.fruits*

J. Kuppast[2] and P. Vasudeva Nayak[1]

1 Department of Studies in Chemistry, Kuvempu University, Jnana Sahydri, Shankarghatta-577 451, Karnataka (India). Fax:-08282-656255, E-mail: university@sancharnet.in

2 Department of Pharmacology, K.L.E.S' College of Pharmacy, Vidyanagar, Hubli-580 031.(India) Fax: 0836-371694. E-mail: klescoph@sancharnet.in

Various extracts of *Cordia dichotoma Forst.f.* fruits were tested for diuretic activity in rats. The parameters studied on individual rat were total urine volume, urine concentration of Na^+ and K^+. In the present study petroleum ether, solvent ether and butanol extract of *Cordia dichotoma* fruits 300mg/Kg of body weight showed increase in urine volume and cat ion excretion. Fursemide was used as a reference diuretic.

CP 56 Pharmacognostic studies on *Ecbolium viride* (Forssk) alston

D .Shyam Sundar [1*], S.Kanagaraj [1], P. Jayaraman [2]

1. Department of Pharmacognosy, Madras Medical College Chennai -3.
2. Plant Anatomy Research Centre, Chennai -45.

Ecbolium viride (Forssk) Alston of Acanthaceae is recorded as udajati in Hindi and Nellambaram in Tamil. In Indian system of Medicine the whole plant is used in dysuria , gout ;decoction of leaves for structure; roots in treatment of`jaundice, menorrhagia and rheumatism. The present contribution pertains to the pharmacognosy of whole herb covering Anatomical features, Quantitative microscopy, Powder microscopy and Preliminary Phytochemical screening.

Transectional profile of leaf showed prominent midrib, projecting into large hemispherical abaxial body. The lamina is dorsiventral and hypostomatic with thin unistratose palisade cells. The vascular bundle of the midrib is U- shaped. The foliar stomata are diacytic, anticlinal walls of the epidermal cells are wavy, peltate glandular trichome very frequent on the epidermis .The petiole is plano-convex outlined with U –shaped vascular strand and two adaxial smaller accessory strands. Young stem with heterogeneous cortex and thin closed vascular cylinder and wide pith are characteristic. The old stem has distinct growth rings. Secondary phloem with thin tangential bands of fibres and phloem elements are diagnostic. The root has narrow periderm, aerenchymatous cortex, dense solid core of secondary xylem and thin phloem unsheathing the xylem. Large lithocysts with oblong cylindrical cystoliths are wide spread in all parts of the plant, including root.

The powdered drug revealed the presence of sporadic concentric starch grains, libriform fibres, narrow cylindrical vessels and oblong cylindrical cystoliths.

Preliminary phytochemical screening revealed the presence of presence of alkaloids, sterols, flavanoids, terpenoids , saponins, tannins and phenolic compounds.

CP 57 Antiimplantation and antioestrogenic activity of fruit and aerial part of *Aristolochia bracteolata Lam.* in female wistar rats.

M.N.Satish Kumar., Mukul Prakash*, Janmeya Jana, T. Subburaj, K.Elango, K.Chinnaswamy and B.Suresh.

J.S.S College of Pharmacy, Rocklands, Ootacamund-643 001 Tamilnadu

Aristolochia bracteolata is used as an antifertility agent in traditional system of medicine. The present investigations were carried to evaluate antifertility activity of fruit and aerial parts of plant extracts at 100 mg and 200 mg doses. Oral administration of the extracts in pre-coital and post coital treatment showed significant activity. Further, results of antioestrogenic study showed significant decrease in uterine weight. From the above findings, it indicated that the antifertility of Aristolochia bracteolata could be due to antioestrogenic property.

CP 58 Pharmacognostical, preliminary phytochemical and pharmacological studies on the leaves of *Pavetta indica* Linn

V. Yasmin*[1], S. Sangeetha[1], R. Gunasekaran[1], K.L. Senthil Kumar[1], D. Baggiya Selvi[2]

1. Padmavathi college of Pharmacy,Dharmapuri,TN-635205
2. Gowtham college of Pharmacy,Bangalore, KN-32

The development of traditional herbal medicine in to a modern drug is of great therapeutic importance. The plant of *Pavetta Indica Linn* was found to have wider therapeutic uses. So as an approach we planned to investigate the various parameters such as pharmacognostical, preliminary phytochemical and pharmacological studies from the leaves of the plant Pavetta Indica Linn. In the pharmacognostical part we investigated the macroscopy, and in the microscopy the transverse section of leaf and cross section of petiole was observed. As ash values are helpful in determining the quality and purity of the crude drugs, the total ash, acid insoluble ash, water soluble ash and sulphated ash was determined under the physicochemical constants. As the next study Preliminary phytochemical investigations such as the purification of solvents, preparation of extracts with petroleum ether, chloroform, ethyl acetate, and methanol was prepared. The phytochemical tests to find out the presence of alkaloids, carbohydrates, glycosides, steroids, saponins, phenolic compounds, proteins, mucilage, flavanoids, fats and triterpenoids was analysed. And finally the pharmacological study such as the gross behavioral and toxicity studies were studied with mice. And anti-inflammatory activity with histamine induced paw edema were rats was also performed. The results showed significant anti-inflammatory activity.

CP 59 Estimation of harmaline content in *Passiflora edulis sims* by HPTLC

K.M. Harsha*., S. Sudhekar Raja, H.C.Manjunatha., S. Manimaran., K.Chinnaswamy., B. Suresh

Department of Phyto Pharmacy and Phyto Medicine, TIFAC CORE in herbal drugs, JSS College of Pharmacy, Ootacamund – 643 001.

Passiflora edulis simi commonly know as passion fruit. Family passifloraceae. The purple coloured flower plant chiefly grown in higher altitude used in folk medicine for stomach ache. The chief constituents of the plant are cyanogenic allosides, cyanogenic glycosides, cyclortane triterpenoids, saponins and alkaloids. The main aim of this study is to estimate the active constituent Harmaline by High Performance Thin Layer Chromatographic Technique using Silica Gel GF_{254} (MERCK) . The chromatogram was developed by applying the standard and the sample in standard dilutions using Chloroform : Acetone : Di ethlyl amine (50:40:10) as solvent system. The plate was scanned at wavelength 351nm by using absorption mode. The RF value of Harmaline in the extract matches with the RF value of standard Harmaline which confirms the presence of Harmaline in the extract. The amount of Harmaline was estimated by comparing the peak areas of standard with the peak areas of sample. The amount of Harmaline present in the extract was found to be 0.085% w/w.

CP 60 Antidiabetic activity of *Cassia auriculta* Linn. seeds

Aruna Pai*, S.S.Jalalpure, M.B.Patil, F.V. Manvi & Shivaji Bamne

*K.L.E.'s College of Pharmacy, Dept. of Pharmacognosy & Phytochemistry, Bangalore-10.

Cassia auriculata Linn. (Family – Caesalpiniaceae) is tall, much branched shrub with large bright yellow flowers ; bark smooth, reddish brown; branchlets finely pubscent leaves. Seeds are ovate,dark brown with hard shiny coat and 10 to 20 in numbers per pod. Plant is widely distributed in dry regions of the central provinces and western Peninsula. It is also cultivated in many parts of India and Shrilanka. The seeds of Cassia auriculata have been documented to possess antidiabetic activity in Ayurveda.To determine if there is a scientific basis for this use, the seeds of C.auriculata were successively extracted with petroleum ether (40 -60°c), chloroform, ethyl acetate, ethanol and water in soxhlet extractor. These extracts were then screened for alloxan (80 mg/kg b.w., i.v.) induced diabetes in albino rats. Blood glucose levels were evaluated at the intervals of initial, 3, 5 and 7 hrs.The animals were continued with this treatment for seven days and again blood glucose level was measured.Tolbutamide (250 mg/kg b.w.,orally) was served as a reference standard.

Petroleum ether extract and ethyl acetate extract showed signifiacnt reduction in blood glucose level while ethanol and water extract failed to reduce blood glucose level.

Petroleum ether extract showed the significant anti-diabetic activity among all the extracts compared to tolbutamide, a reference standard.

CP 61 Anti-allergic Effect of Ethanol of *Tagetes erecta* Linn. Flowers

Mahesh B. Palkar[1]*, K.K. Sreenivasan[2], H. Srinivasa[2] and V.P, Veerapur[3]

1. Dept. of Medicinal Chemistry, K.L.E.S.'s College of Pharmacy, Belgaum - 10.
2. College of Pharmaceutical Sciences, Manipal - 19.
3. SET's College of Pharmacy, Dharwad - 02.

Tagetes erecta Linn. (San: Sthulpushpa) Family: Asteraceae is a stout, branching herb, cultivated as a border-annual in gardens all over Inida. Traditional medical practitioners have reported it as effective remedy in the relief of cough, chest pain, cold and allergic disorders such as asthma and bronchitis with promising results. The private communications reveal that the parts of the title plant were used in the treatment of dermatological condition such as itching, insect bites, scabies. Lack of scientific literature to support the ancient and folk practices/claims prompted us to investigate the activity guided fraction study of the flowers of *Tagetes erecta.*

The central event in an allergic reaction is mast cell degranulation. The influence of the ethanolic extract of the flowers on male albino rat mast cell degranulation induced by an antigen (sheep serum by compound 48/80 was evaluated. Both the allergens used in the present study are the most potent cell degranulator, they causes the release of *denovo* synthesized mediators such as histamine, leukotrienes, prostaglandins etc, from the mast cells. These mediators are responsible for immediate hypersensitivity. The ethanol extract of *T. erecta* produced significant dose dependent inhibition of cell mast degranulation against sheep serum and compound 48 - 80.

In the sheep serum model, the ethanol extract at two doses (200 mg and 400 mg/kg b.w/day was administrated orally for 14 days. The extract at dose of 400 ,g/kg b.w. showed significant protection (65.30 ± 1.81) of mast cell degranulation induced by sheep serum as compared with control group whereas standard drug ketotifen (1 mg/kg b.w. day p.o) exhibited 74.31 ± 1.85. In the other model, oral administration of the ethanol extract at two doses (200 mg and 400 mg/kg b.w/day p.o) carried out for 7 days. The extract at dose of 400 mg/kg b.w showed significant protection (69.92 ± 1.2) of mast cell degranulation induced by compound 48/80, when compared with control tested animals (20.36 ± 1.23), whereas standard drug ketotifen (1 mg/kg b.w/day p.o) exhibited 72.28 ± 1.4.

The Flavonoids quercetin and kaempferol have been proved to be antiallergic compounds. In the chemical constituents such as kaempferol, kaempferol-7-rhamnoside, kaempferitrin, 8-hydroxy quercetagetin and other phenylated flavonoids were reported to present in the plant. The antiallergic activity of the title plant may be attributed to the flavonoid constituents of the ethanol extract.

CP 62 Hepatoprotective activity of fruits of *Garcinia indica* Roxb.

V.I. Hukkeri., R.V. Karadi., Marina D'souza., and Mirza Rafiullah Baig*.

Department of Pharmacognosy and Phypochemistry, K.L.E'S College of Pharmacy, Vidyanagar, Hubli – 580 031. Karnataka. India.

The fruits of *Garcinia indica* (Family : Guttiferae) is popularly known as a refreshing drink in Goa. The Garcinia species prefers evergreen and semi evergreen forest. Seventeen species of them are endemic in India of which 7 are found in the Western Ghats, 6 in the Andaman and Nichobar islands and 4 in the north-east India. Out of these the most prevalent species are *G. cambogia* and *G. indica*.

The *Garcinia indica* improves appetite and allays thirst, and used as anthelmintic, cardiotonic, tumours, pains and heart diseases. It is also used in liver disorders. In spite of its uses in liver disorders, no systematic and scientific studies on liver protecting activity have been reported yet. In current studies an effort has been made to establish hepatoprotective activity of ethanolic and aqueous extracts of fruit rind of *Garcinia indica* Roxb.

In this study Phenobarbitone sodium injection IP to determine the sleeping time and Carbon tetrachloride (CCl_4) induce hepatotoxicity are used as the parameters to evaluate Hepatoprotective Activity.

From the result both ethanolic and aqueous extract showed significant Hepatoprotective Activity by reducing sleeping time which was highly increased in CCl_4 treated mice.

CP 63 Hypolipidemic activity of aqueous extract of *Withania coagulans dunal* in high fat diet model

S.Hemalatha[1]*, A.K.Wahi[1], P.N. Singh[1] & J.P.N. Chansouria[2]

1. Department of Pharmaceutics, Institute of Technology
2. Center for experimental surgery & medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi -221005.

Withania coagulans dunal (Family: Solanaceae) commonly known as Indian cheese maker is a rigid, grey under shrub occurring in drier parts of India. Aqueous extract of fruits of *W. coagulans* has been shown to exert hepatoprotective, anti inflammatory and antidiabetic activity. In our earlier studies the aqueous extract of fruits of *W. coagulans* was found to reduce the cholesterol level in streptozotocin induced diabetic rats. In the present study attempt has been made to investigate the hypolipidemic activity of aqueous extract of *W. coagulans* in triton and high fat diet induced hyper lipidemic models.

The dried fruits were purchased from the market in Varanasi and its identity was authenticated. The hypolipidemic activity of the aqueous extract of W. coagulans was first screened in Triton (200mg/kg;i.p) induced hyperlipidemia in rats. The serum cholesterol was estimated and proceeded for high fat diet model. Different groups of albino rats (175-225gms) Charles foster strain of both sexes were administered with aqueous extract of W. coagulans (1g/kg; po) and Navaka guggulu along with high fat diet for 7 weeks. The change in body weight, serum cholesterol, serum lipoproteins atherogenic index, hepatic cholesterol and hepatic lipid peroxidation (LPO) were determined after 7 weeks and compared with untreated and normal rats. The histopathological studies of liver were done.

The aqueous extract of W. coagulans (1g/kg;po) showed 15% reduction in serum cholesterol in triton induced model. Administration of aqueous extract of W. coagulans along with high fat diet showed significant decreases in body weight, serum cholesterol and serum lipoproteins in rats and was comparable with that of Navaka guggulu. Histopathalogical studies reveal the presence of microvesicular changes in the extract treated livers. The observation of the present study scientifically validates the hypolipidemic activity.

CP 64 Development and screening for its anti microbial potential of a polyherbal ointment

Mohd. Imtiyaz Ahmad*, Gowri, Duraiswamy B., & Suresh. B.

Department of Pharmacognosy', J.S.S. College of Pharmacy, Ootacamund.

The leaves of the *Leucas aspera* Spreng of Labiate, and the stem bark of *Madhuca longifolia* (Koenig) Macbride of Sapotaceae have been used in tradition medicine to cure various skin disorders. In order to prove the claim and to have a formulation containing these plant materials, the powders of the selected materials were mixed in a definite ratio (2:1) and incorporated into an ointment base to prepare an ointment. The methanol and aqueous extracts of the individual plants powders and the formulation containing the methanol extracts of the selected plant powders were then subjected for anti microbial screening against *Bacillus subtilis* NCIM-2349, *Staphylococcus aureus* NCIM-2492, Escherichia coli NCIM-2345, *Salmonella typhi* (strain obtained from Calicut medical college) and antifungal potential against *Aspergillus niger* NCIM -590 and *Candida albicans*. The standard drug taken was Ampicillin trihydrate (1mg/ml) for antibacterial activity and Amphotericin B (1mg/ml) for anti fungal activity.

The methanol extract of the leaves of Leucas aspera Spreng was showing a comparable and significant antibacterial against all the gram positive and gram negative strains which was comparable with the standard drug Ampicillin trihydrate. However, the aqueous extract was showing a better activity against E.coli than that of the methanol extract. The methanol extract of the stem bark of Madhuca longifolia was showing a significant activity against all the bacterial strains than the aqueous extract. The methanol extracts of plants were selected for formulation and the antibacterial activity of this was the highest. The methanol extracts of the plants and the formulation exhibited good activity against both the antifungal strains.

CP 65 TLC densitometric method for the quantification of β-carotene, β-sitosterol and lupeol in *Helicteres isora* and *Quisqualis indica*

Sachin Pathak*, Milind Bagul, S.C. Pal, Harish Padh, M. Rajani

B. V. Patel Pharmaceutical Education and Research Development, (PERD) Centre, Thaltej, Ahmedabad – 380 054

Quisqualis indica Linn. (Family: Combretaceae) is a creeper commonly cultivated in gardens in Malaya and India. Traditionally fruits and seeds are used as a anthelmentic, antidiarrohoeal and antipyretic. *Helicteres isora Linn.* (Family : Sterculiaceae) is a sub-deciduous shrub or small tree and is widely distributed throughout India. In Ayurveda Helicteres isora is used as antidiabetic and anthelmentic.

In the present study we report our work on the development of TLC densitometric method for quantification of β-carotene, β-sitosterol and lupeol. Developed methods were used for the estimation of these compounds from leaf, stem and fruit of Q. indica, and leaf of H. isora. The methods were validated for precision (interday and intraday), repeatability and accuracy. Recovery study was conducted at two different levels.

The content of β-carotene was found 0.25 %, 0.08 % and 0.13 % (w/w) in *Q. indica* leaf, fruit and H. isora leaf respectively. β-carotene was not detected in the stem of Q. indica. β-sitosterol was 0.024 %, 0.035 %, 0.022 % and 0.014 % (w/w) in Q. indica leaf, stem, fruit and *H. isora* leaf respectively. The content of lupeol was 0.036 %, 0.015 %, 0.069 %, 0.011 % (w/w) in *Q. indica* leaf, stem, fruit and H. isora leaf respectively. Lupeol and b-sitosterol were simultaneously estimated. The proposed HPTLC methods for the estimation β-carotene, β-sitosterol and lupeol were found to be simple, precise, specific, sensitive and accurate and can be used for routine quality control of Q. indica leaf, stem, fruit and H. Isora leaf and may be suitable for other plant materials as well.

CP 66 Hepatoprotective activity of crude methanolic extract of bark of *Grewia asiatica* Linn

T. Satyanarayana, B.V.S.K. Devarayalu

Department of Pharmacognosy, Andhra University, Visakhapatnam 530 003

The species *Grewia asiatica* (Family : Tiliaceae) is a traditional plant medicine and as remedy for liver cirrhosis. The fruit is good for troubles of throat and helps removal of foetus. The aim of the present study was to test hepatoprotective activity of the crude extract bark of G. *asiatica* using CCl4 - induced hepato toxic method in rabbits.

Crude methanolic extracts of bark (250 and 500 mg/kg) were administered orally along with acacia mucilage to albino rabbits of either sex (1.5 to 2 kg) 1hr. prior to induction of hepatotoxicity. Hepatotoxicity is induced by administering CCl4 (0.75ml/kg) orally. Blood samples were collected from the marginal ear vein before the treatment and after, 1,4 and 7 days of treatment and were analysed to determine the serum Glutamate Oxoloacetate Transaminase (SGOT) and Glutamate Pyruvate Transaminase (SGPT) and serum bilirubin levels.

The results should that both dose levels of the methanolic extract showed the percentage increase in SGOT. SGPT and Serum bilirubin in animals of Groups B and C, which received both methanolic extract and CCl4 at different dose levels and was much less then the percentage increase observed in Group A which received only CCl4. These results indicated a partial protection to liver damage by G. *asiatica* at these two dose levels.

In conclusion the bark extract exhibited hepatoprotective activity and suggesting that the extract is worth examine further to isolate the active constistuments responsible for this activity. This investigation is in process.

CP 67 Tissue culture studies on *Withania sominifera* for production of withanolides

Sachin Bhaskar , J. S. Sudha, Raman Dang, B.G. Shivananda, Salma Khanam

Al-ameen College of Pharmacy, House Road, Near Lalbagh Main Gate, Bangalore 560 027

In the present study , tissue culture on Withania somnifera described viz., callus initiation, organogenesis, regeneration, growth phase studies and microtomy studies was carried out. Study includes identification and estimation of withanolides, identification of alkaloids from different condition of Withania somnifera. Wild plant parts and cultivated plant parts are extracted and compared with callus, hairy root extract for withaferin A content by HPLC method.

Seeds were germinated under aseptic conditions and was observed that half basal medium was most suitable for seeds germination. Murashigae and Skoog basal medium supplemented with 0.2 mg / L 2,4 – D and 0.2 mg/L kinetin gave good callusing. For organogenesis M. S. basal media supplemented with 2 mg/L IAA and 2 mg/L IBA was found good for organogenesis using leaves as explant. Root formation was observed and root nature was thick and long.

To understand cytoarchitecture of root callus and shoot callus they were subjected to microtomy. By histochemical analysis the total protein content, metabolic activity of cells, RNA content, were investigated. Root callus was active in all aspect compared to shoot callus.

Quantitiative estimation of withaferin A was carried out using HPLC which revealed the presence of high content of withaferin A in cultivated root extract. Callus and hairy root extracts did not show presence of withaferin A.

Study was successful in standardizing the media for tissue culture, aseptic germination, callus intiation, organogenesis, regeneration and hairy root culture studies of Withania somnifera.

CP 68 Antimicrobial potential of the extracts of *Citrus lemon* peel

Alok Kumar Upadhyay*, Gowri, Duraiswamy B., & Suresh. B.

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ootacamund

Al-ameen College of Pharmacy, House Road, Near Lalbagh Main Gate, Bangalore 560 027

Citrus lemon (Linn.) Burm. F. commonly distributed throughout India, cultivated in plains and hills. The peel of the lemon fruit of this plant has been used for its bactericidal activity. Methanol and aqueous extracts of the Citrus lemon peel were investigated for antibacterial potential against *Bacillus subtilis* NCIM-2349, *Staphylococcus aureus* NCIM-2492, *Escherichia coli* NCIM-2345, *Salmonella typhi* (strain obtained from calicut medical college) and antifungal potential against Aspergillus niger NCIM - 590 and *Candida albicans*. The standard drug taken was ampicillin trihydrate (1mg/ml) for antibacterial activity and Amphotericin B (1mg/ml) for anti fungal activity. The extracts were prepared by dissolving each of 100 mg of methanol and aqueous extract in 10 ml of dimethyl sulphoxide (DMSO). A standard drug, ampicillin trihydrate (1 mg/ml) was prepared in DMSO for antibacterial activity and standard amphotericin B (1 mg/ml) in DMSO for antifungal activity. The methanol extract of the citrus lemon (Linn.) Burm. f. showed significant activity against all the strains than the aqueous extract except *E. coli*. for which the aqueous extract was showing better activity than the methanol extract.

CP 69 Phytochemistry & pharmacognosy *in vitro* anti-platelet activity of *Hibiscus vitifolius* flowers

M.C. Sudharshan*, A. Adil Basha, D. Chamundeeswari, J. Vasantha

Sri Ramachandra College of Pharmacy, Sri Ramachandra Medical College & Research Institute (Deemed University), Porur, Chennai 600 116.

Hibiscus Vitifolius Linn (Malvaceae) commonly called as *Manjal Tuthi* is a traditional plants drug having anti diabetic activity, anti inflammatary and hepato protective activity. An attempt has been made to study the effect of the various extracts of flowers of *Hibiscus Vitifolius.* (ie. hexane, chloroform and methanol in 250, 125, 62.5µg/ml) on blood platelets were studied by invitro method using, platelet rich plasma in presence of ADP. Aspirin 100 µg/ml was used as standard. The inhibition of platelet aggregation was found to be remarkable at 250 µg/ml concentration in chloroform & hexane fraction compared to aspirin, where as methanol fraction showed no platlet aggregation. The above results may be due to the presence of flavonoids, alkaloids and quinone in chloroform extract.

CP 70 Pharmacognostical and phytochemical profiles of *Rhododendron arboreum* leaf

Tamizh Mani.T, Pulok K Mukherjee,Supriya Datta* , Subburaj.T, and Suresh.B.

Department o Pharmacognosy, JSS College of Pharmacy, Rockland's, Ooty 643 001

Rhododendron arboreum belongs to the family Ericaceae. The leaf and leaf extract used to relieve headache, diarhoea and dysentery. In a preliminary screening it has reported matured dried leaf have CNS effects in animals, in homeopathic material medica, the tincture of dried leaf has been mentioned to used in gout and rheumatism. In addition Ayurvedic preparation "asoka arista" containing *Rhododendron arboreum* possesses oxytocic, estrogenic and prostaglandin synthetase inhibiting activities. Flowers of the plant have been claimed for anti-inflammatory activities. The present investigation deals with macro and microscopic characters of leaf along with studies of physical constants like ash values, extractive values and qualitative phytochemical analysis and thin layer chromatography and HPTLC finger print analysis also studied. This study will help in Ayurvedic industry for correct identification of this plant.

CP 71 Chemical standardization of *Caesalpinia crista* by HPLC

K. Sumanth Prabhu, Prasanna ShamKhandige* and Saurabh. K. Banerjee.

Department of Pharmaceutical Chemistry,
J.S.S. College of Pharmacy,
Ootacamund 643 001 Tamilnadu.

Caesalpinia Crista Linn commonly known as Gajga, fevernut, Sagar Gota etc belongs to the family Ceasalpinaceae.[3] The seeds oblongs, lead coloured 1.3cm long have been used by the ancients in the medicine like powdered seeds with sugar and goat's milk are reported to cure liver disorders[3]. The seeds kernels are used as tonic in intermittent fevers, asthama and colic. The seeds are reported to contain as many as 20 amino acids, among which many being essential amino acids.[3]

Neutraceuticals are among the latest of the pharmaceuticals under which class comes various vitamins, antioxidants and some proteins. Off late some new natural products are under study for the vitamins, antioxidants etc. Since natural products are more advantageous over the synthetic ones, we were interested to study the various seed extracts for their amino acid content by analytical technique like TLC, PTLC and HPLC for standardization, which would aide in the further study and characterization of Ceasalpinia Crista.

CP 72 Pharmacognostic evaluation of *Achyranthes aspera, A. bidentata, Aerva lanata* and *Celosia argentea*

T. Vetrichelvan, M. Jegadeesan[1] and H. Amudhavani

Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319(T.N.), [1]Department of Siddha Medicine, Tamil University, Thanjavur-613 005.

An ethnobotanical survey undertaken by the author in Tiruchirapalli District revealed that some plant species belonging to the family Amaranthaceae are more commonly used as folk medicines against renal dropsy, rheumatoid arthritis and diabetes mellitus. The family Amaranthaceae has about 121 medicinal plants throughout the world. Out of these 22 medicinal plants have been reported to be present in India and are known to have therapeutic properties. Among them Achyranthes aspera L. (AA), Achyranthes bidentata Blume (AB), Aerva lanata (L.) Juss. ex Schultes (AL) and Celosia argentea L. (CA) are commonly available in this area. On perusal of literature, it was found that Pharmacognostical and Phytochemical works on AA, AB, AL and CA are lacking. Hence, the present work was undertaken with a view to investigate anatomical features, physico-chemical constants, IR and HPLC spectral datas and phytochemical screening on the above four medicinal plants which are used in Indian Traditional and Folk medicines.

Pharmacognostical studies establishes the anatomical features, quantitative leaf constants, physicochemical parameters, fluorescent characters, qualitative phytochemical screening and finger print with IR and HPLC for the plants of AA, AB, AL and CA. The IR spectra of benzene and alcoholic extract of AA and AB revealed similar and distinctive bands. Among the dissimilarities are absence of peaks at 668, 1261, 1631, 2342, 2360 and 3856 cm-1 in benzene extract of AA while they are present in AB. The number of peaks in alcoholic extract of AA are also more and could be distinguished by peak position and their intensity. The IR spectral data of all the four species showed the presence of aromatic (1600 cm-1), -OH bonded (3330 cm-1), compounds in all the extracts. By comparing with this datas, folklore practitioner or a person related to this field can be identified the particular plant without any difficulty.

CP 73 Extraction, characterization and comparison of essential oil of *Zanthoxylum alatum* & *Zanthoxylum rhetsa* (syn. Z. limonella) Fam. Rutaceae

Shantanu Kale, Santosh Tambe, Prathamesh Pathak*

M G V's Pharmacy College, Panchvati, Nashik 422 003

Zanthoxylum alatum, a species growing in the Himalayas, figures prominently in Tibeti and Nepali cooking. Indian species, *Z. rhetsa* (syn. *Z. limonella*), is a species growing in coastal south India and Maharashtra (also used in spices). The typical flavour of *Zanthoxylum* species is due to essential oils which are stored in the pericarp (fruit wall, shell) but not in the seeds, and as a rule, it is mostly composed from terpenoids, but the exact composition varies considerably among the species, and sometimes even within the species.

In this work essential oil was extracted from seed carpels *Zanthoxylum alatum* and *Z. rhetsa* and characterize terpenoids present in it were characterized and compared with GC, GC-MS, and HPTLC.

GC and GC-MS of Z. alatum shown presence of a-pinene, b-pinene, b-myrcene, limonene, 3-carene, linalool, carvone, 2-undecanone, 4 isopropyl benzyl alcohol, a-copaene, methyl cinnamate, 2 –tridecanone, caryphyllene oxide, 4-phenylaniline, 7,11-dimethyl 1,6,10-dodecatriene.

Indian species, *Z. rhetsa* (syn. Z. *limonella*), the essential oil (3.7%) has been shown to consist mainly of monoterpene derivatives: Sabinene, limonene,

pinenes, para-cymene and terpinenes b-phellandrene, linalool furthermore the monoterpene alcohols 4-terpineol α-terpineol and 1,2 dimethyl cyclohexane

Dominating constituent of *Z. alatum* was shown to be linalool 57%, methyl cinnamate 9.61% limonene 8.62%. Dominating constituents of Z. rhetsa was shown to be b-phellandrene(16.05%), 1,2 dimethyl cyclohexane (15.83%), linalool (9.42%). *Z. alatum* essential oil exhibited 7 peaks with R_f value 0.1, 0.17, 0.23, 0.33, 0.37, 0.46, 0.55 . Z. rhetsa essential oil exihibited 9 peaks with R_f value 0.09, 0.15, 0.19, 0.28, 0.34, 0.41, 0.51, 0.68 and 0.87

CP 74 Investigation of the free radical scavenging activity of *Nyctanthes arbortristis* flowers

Santosh Tambe, Shantanu Kale. Yogesh Ushir, Santosh Chhajed*

M G V's Pharmacy College, Panchvati, Nashik 422 003

The *Night Jasmine* plant *Nyctanthes arbortristis* Family : *Oleaceae* grows widely in India. It produces small fragrant flowers with white 4-8 lobes and bright orange tubes. The active principles of the flowers of Nyctanthes arbor-tristis are Flavonoid glycosides and Phenolic substances. The presence of Natural antioxidants has been confirmed in soybean, garlic red wine, green tea and in flowers of hawthorn. Limited information is available on antioxidant property of flower of *Nyctanthes arbortristis*

In present work the free radical scavenging activity of methanolic, ethanolic and aqueous extracts from *Nyctanthes arbortristis* flower has been determined by EPR using DPPH (1,1-dipheny1-2-picrylhydrazyl) radical scavenging method. Investigation has also included Quercetin as a selected constituent of *Nyctanthes arbor-tristis flower.*

The electron paramagnetic resonance spectra of extract have shown presence of scavenging activity. The DPPH radical scavenging activity was found in methanolic extract

HPTLC fingerprinting of ethanolic methanolic extract of *Nyctanthes aobortristis flower* was carried out with the solvent system Ethyl acetate: Formic acid: Glacial Acetic Acid: Water (100:11:11:26)., shown 5 peaks with Rf 0.04, 0.07, 0.11. 0.26 0.35.

HPTLC Finger printing of etahnolic and methanolic extracts of *Nyctanthes arbortristis flowers* have shown 0.16%, 0.12% of Quercetin respectively.

CP 75 Evaluation of anti-inflammatory activity of *Desmodium gangeticum* Linn

Nilambari Deshkar*, Shivkanya Jaju, S.S Gurav, D.P. Hase, N.J. Duragkar, A.T. Patil, P.R. Itankar.

Nilambari Deshkar, Dept. of Pharma. Sciences, Nagpur University Campus, Amravati Road, Nagpur 440 033

Desmodium gangeticum Linn. belonging to family Leguminosae is popularly known as 'salparni' found throughout India. The shrub is also known as Salpan (Hindi). Salwan (Gujarathi), Pruthkaparni (Sanskrit), Orilla (Tamil)[1].

It is well known in Ayurvedic system of medicine and traditionally used to treat fever, pain, pyrexia, rheumatic arthritis, respiratory diseases[1,2,9,12] etc. Extracts of *Desmodium gangeticum* are effective on central nervous system[3]. The root is hot and bitter aphrodisiac, anthelmintic, cures typhoid fever. Piles. Inflammations, Asthma and bronchitis[4]. The constituents pterocarpan[5,8]desmondin[6], pterocarpanoids, gangetinin, alkaloids[7] and are reported to the present. An experimental was plant to evaluate its anti-inflammatory activity.

Desmodium gangeticum stem and leaves were defatted with petroleum ether (60-80°C) and successively extracted with chloroform and ethanol using soxhlet apparatus. The marc was then macerated with ethanol+water (1:1). Preliminary phytochemical screening of all the extracts was carried out.

The anti-inflammatory activity of *Desmodium gangetium* was studied by using carrageenan induced rat hind paw edema model 10,11. Albino rats of either sex weighing 150-250g were used different groups. One group served as control was vehicle treated. Second group was administered with Ibuprofen (100mg/kg). Test extracts were fed orally at doses of 100mg and 200mg kg body wt. Ibuprofen (100mg/kg p.o) was taken as standard drug. After one hour of the above treatment inflammatory edema was induced by injecting 0.05ml of 1% w/v solution of carrageenan in saline in planter tissue of all animals. The paw edema was measured by digital plethysmometer at 0,1 and 3 hr. duration.

Carrageenan induced oedema is a two phase event. First phase is attributed to release of histamine and serotonin and second phase to prostaglandin release along with migration of leukocytes into inflamed site[11].

The extracts were found to contain alkaloids, saponins, triterpenoids etc. The hydroalcholic extract of stem and leaves of *Desmodium gangeticum* showed maximum anti-inflammatory activity in carrageenan induced rat paw edema. The inhibition of edema

was found to be in the order of Hydroalcholic extract>ethanolic extract> chloroform extract.

The results demonstrate that hydroalcholic extract exhibits significant anti-inflammatory activity. The percentage of inhibition was found to be effective as compared with standard drug Ibuprofen.

Further evaluation will be done by using preparative TLC of hydroalcoholic extract. Column chromatography, IR, NMR, MASS spectroscopy will be done to isolate the constitute responsible for anti-inflammatory activity.

CP 76 — *In-vitro* anti-inflammatory activity guided fractionation of aerial parts of *Melothria maderaspatana* (Linn) Cogn by HRBC membrane stabilisation

B.Lakshmi Priya*, Iman R. Ahmed, Chithra Rajan, Sharon Serah Varghese, K. Shalini, D.Chamundeeswari and J. Vasantha.

Sri Ramachandra College Of Pharmacy, Sri Ramachandra Medical College And Research Institute, Porur Chennai 600116.

Melothria maderaspatana (Linn) Cogn, (Cucurbitaceae) commonly called as musumusukkai in Tamil, Agumaki in Hindi, Noogudosa in Telugu, Mukkalpeeram in Malayalam, a plant drug of siddha medicine, is a prostrate or climbing herb, distributed throught India and widely consumed by south Indians. By preliminary phytochemical screening the plant is found to have alkaloids, steroids, glycosides, coumarins, flavanoids, tannins and phenolic compounds. As the *in-vivo* anti-inflammatory activity has been reported, a futile attempt has been made to study the *in-vitro* anti-inflammatory activity of aeriel parts of Melothria maderaspatana (Linn) Cogn, by performing successive extractions using solvents of increasing polarity (ie hexane, chloroform, ethylacetate, methanol) by HRBC membrane stabilization method.

The results showed effective stabilization of the HRBC membrane in the presence of the drug. The hexane, chloroform, ethylacetate, methanol, alkaloidal and non-alkaloidal fractions of methanol extract used in the concentration of 500mg/ml, 200mg/ml, 100mg/ml, 50mg/ml and 10mg/ml were tested for the study.

The methanol extract, chloroform extract, ethyl acetate extract and alkaloidal fraction of methanol extract showed profound anti – inflammatory activity than the hexane extract and the non-alkaloidal fraction of methanol extract. The results were compared with the standard drug, prednisolone (100mg/ml).

A time related study was also conducted with all the fractions at 100mg/ml, in which the anti-inflammatory activity due to methanol extract showed an increase with time, where as the chloroform extract, ethyl acetate extract and the alkaloidal fraction of methanol extract showed a biphasic effect, with a maximum activity till 30 minute exposure with the drug and a decrease in activity later with respect to time.

CP 77 — Isolation and preliminary phytochemical investigation & anti-bacterial potential of the whole herb of *Bidens Piolosa L.* Var (Asteraceae)

Akalanka Dey[1], S. Parimalakrishnan, K. Ramya, J. Suba Devi*, and S. Rajendran[2]

1. Department of Pharmacy, Annamalai University, Annamalai Nagar – 608 002 (T.N)
2. Department of Microbiology, Annamalai University, Annamalai Nagar – 608 002 (T.N)

The herbs *Bidens pilosa* Linn (Family: Asteraceae) are commonly growing in rainforest and topical areas especially in Kerala (South India) is popularly known as " beggar's tick" has a wide reputation for their versatile medicinal uses in south America, Africa, Caribbean, Philippines, Brazil and Peru. [1]This plant is used in the treatment of wounds against inflammation[2], chronic gastric ulceration[3], leukemia [4] and also hepatoprotective[5]. From the ancient literature reported that it is being used in headache, mixture of decoction of the plant with lemon juice are used in angina, dropsy hepatitis, soar throat and water retention. Infusions are also used in emmanagogue, anti-dysentric and to alleviate chills.

Bidens pilosa plant was collected from Thenmalai Kerala, South India by one of the author and its authenticity was verified by Department of Botany, Annamalai University, Annamalainagar. The five pathogenic organisms were collected from Rajah Muthiah Medical College, Department of Microbiology, Annamalai University.

The present study comprises of preliminary phytochemical screening and antimicrobial activity using various fractions of water and ethyl acetate and n-Hexane against five pathogenic bacteria [*S.aurers* (MTCC 740), *S. luteus* (MTCC 849), *S. typhi* (MTCC 98), P. aeruginosa (MTCC 741), *K. pneumoniae* (MTCC 109)]. The n-Hexane, ethyl acetate and water extracts of *Bidens pilosa* obtained by continuous extraction using soxhlet apparatus. The extracts were tested for its effect on five pathogenic bacteria by Disc Diffusion method[6]. Among the three extracts ethyl acetate extract showed highest inhibitory effect against gram negative organisms.

CP 78 Extraction, phytochemical screening and antifungal activity of the whole herb of *Bidens Pilosa* Linn. Var (Asteraceae)

S. Parimalakrishnan[1], K. Ramya*, J. Suba Devi, Akalanka Dey, and S. Rajendran[2]

1. Department of Pharmacy, Annamalai University, Annamalai Nagar – 608 002 (T.N)
2. Department of Microbiology, Annamalai University, Annamalai Nagar – 608 002 (T.N)

The herbs *Bidens pilosa* Linn. (Family: Asteraceae) is an erect annual or perennial herb without branching, are widely growing in full sun, where the soil is relatively dry and infertile, and so commonly called as "Framer's Friend"[1]. Native range is from temperature and tropical America, but introduced early to the pacific and parts of Asia like Kerala (South India). Due to their high value of medicinal properties it is used for antimicrobial[2], Paw edema[3], antirheumatic[4], and gastric ulceration[5]. Commonly decoction of the plant was drunk for cough and juice of leaves dropped into the ear for conjunctivitis, in Bahamas used in the treatment of cancer, carminative and diuretic, whereas, in Mexico used for hemorrhoids, jaundice, and inflammation. From ancient literature report, observed that it is used in snakebites, malaria, in abortion, astringent, diaphoretic, weight loss, hypotensive and diabetes. Infusions also have been used as a tonic and stimulant[1].

Bidens pilosa Linn. plant was collected from Thenmalai Kerala state (South India) by one of the author and its authenticity was verified by Department of Botany, Annamalai University, Annamalainagar. The five pathogenic fungi were collected from Rajah Muthiah Medical College, Department of Microbiology, Annamalai University, Annamalainagar.

The study comprises with extraction, phytochemical investigation and anti-fungal activities, were carried out with different fractions of the n-hexane, ethyl acetate and water. The extraction was done by hot continuous process using soxhlet apparatus. The extracts were tested against five pathogenic fungi [*M.gypsium, A.flavus, A.fumigatus, Mucor sp.* and *C.albicans*] by Disc diffusion method[6]. The ethyl acetate extract has shown a highest inhibitory effect when compared to the other two extracts against *Microsporum gypsium.*

CP 79 Pharmacognostical evaluation of *Aporosa lindleyana*

Shrishailappa Badami, Om Prakash*, Sujay R. Ravi Subburaju T, Anand Tengli and Suresh B.

JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

Several members of species *Aporosa* (Euphorbiaceae) are being used traditionally for a wide variety of ethnomedical properties. *Aporosa lindleyana* root is used in jaundice, fever, headache, excessive thirst and seminal losses. Its hypoglycemic effects and low toxicity (high LD_{50}) are reported. Due to its vast use in the folklore, the present investigation was undertaken to standardize the root of *Aporosa lindleyana* by carrying out various pharmacognostical characteristics.

The fresh root was dried, powdered and extracted successively with petroleum ether, chloroform, ethyl acetate and methanol in a Soxhlet extractor for 18h. The extracts were concentrated under reduced pressure at low temperatures. The extractive values of these successive extracts were calculated. Ash and extractive values were determined according to I.P.

The extracts were subjected to chemical tests for the identification of the phytoconsitituents. The HPTLC studies were also performed and the suitable solvent system, R_F values and the percentage of the constituents in each extract were determined. The histo-chemical colour reactions of the transverse section of the root were studies. The behavior of the powdered root with different chemical reagents and fluorescence characters of the powdered bark and the extracts were observed under UV (254 nd 366nm) and visible light.

Successive Extractive Values (%): Petroleum Ether (40-60°), 0.2083; chloroform, 0.3626; ethyl acetate. 0.260; methanol, 10.01. Ash and Extractive Values: Total ash, 2.030; Acid insoluble ash, 0.319; Water-soluble ash, 0.6215; Sulphated ash, 2.125; from ethanol extractive, 7.013 land from distilled water extractive, 8.2525. Phytochemical tests indicated phenols,tannins, proteins, saponins and glycosides in ethyl acetate extract, lannins, saponins, carbohydrates, phenolic compounds and glycosides in methanol extract. In HPTLC, CCl_4 : Ethyl acetate (97:03) was found to be the better solvent system for the separation of constituents for the petroleum ether extract. Similarly the suitable solvent systems were found out for the other extracts. Fluorescence characteristics, histochemical studies and histology of the root studied will be presented. In conclusion the present study may be useful to supplement information in regard to its identification and standardization.

CP 80 Wound Healing activity of *Redia floribunda*

K. Hemamalini, K.Umasankar, M.Shiva Kumar,P. Sridevi, M.Vimal Kumar Varma.

Smt. Sarojini Ramulamma College Of Pharmacy A.P Periya College of Pharamaceutical Science For girls, Trichy.

The present study was carried out to assess the wound healing activity of *Redia floribunda*. Since it is used for the treatment of wounds in traditional system of medicine. From the results it was found that the ethanolic extract and fractions of *Redia floribunda* possess significant wound healing activity, which was established by its study on various models like excision wound, incision wound.

Thus the present study highlights the importance of the plant *Redia flouribunda* for its wound healing property.

CP 81 Antioxidant studies on the alcoholic leaf extract of *Annona squamosa*

I.S.R. Punitha*, Annie Shirwaikar, K. Rajendran, and C. Dinesh Kumar

Department of Pharmacognosy, College of Pharmaceutical Sciences, Manipal, Karnataka 576 119

Antioxidants are nutraceuticals, whose deficiency states are associated with numerous dreaded diseases such as diabetes, cataracts, rheumatoid arthritis, etc. The study was conducted for screening the antioxidant potential of the alcoholic leaf extract of the plant *Annona squamosa* commonly known as custard apple (Family- Annonaceae). Invitro antioxidant studies were carried out using five models viz. DPPH, ABTS, Nitric Oxide, Superoxide dismutase and lipid peroxidation models. Successively increasing concentrations of the extract were estimated for its free radical scavenging activity. The decrease in thiobarbituric acid reactive substances (TBARS) and increase in reduced superoxide dismutase (SOD), nitric oxide, DPPH and ABTS free radicals clearly demonstrated the antioxidant property of ethanolic extract of this plant. The ethanolic extract was found to decrease the free radicals formation in all the five *in vitro* models.

CP 82 Antidiabetic studies of custard apple leaves in Type-2 diabetic rats

K. Rajendran*, Annie Shirwaikar and C. Dinesh Kumar

Department of Pharmacognosy, College of Pharmaceutical Sciences, Manipal, Karnataka 576 119

The claim by some tribal populations in parts of Northern India that the young leaves of the Custard apple tree, *Annona squamosa* L. (Annonaceae) has antidiabetic properties was investigated. Diabetes mellitus was induced with streptozotocin-nicotinamide and graded doses of the alcoholic leaf extract suspended in gum acacia were administered to normal and experimental diabetic rats for 12 days. Fasting plasma glucose levels, serum insulin levels, serum lipid profiles and changes in body weight were evaluated in normal rats while liver glycogen levels were evaluated additionally in diabetic rats. The diabetic groups treated with the alcoholic leaf extract were compared with standard glibenclamide. The difference between the experimental and control rats in lowering the fasting plasma glucose levels was statistically significant ($P<0.05$) in diabetic rats. Significant difference was also observed in the serum insulin levels, serum lipid profile, liver glycogen levels, and also histopathological studies were estimated in diabetic rats. The findings showed the significant antidiabetic potential of the extract in ameliorating the diabetic conditions in diabetic rats. No significant effects were found in the normal rats.

CP 83 Antimicrobial activity of leaf extract of *Capparis sepiaria*

Elayaraja.K*, Preethi.R, Abinaya.S, Lakshmipriya.D, Veeramanikam.C, Puratchikodi.A and Selvamani.P.

Department of Pharmaceutical Engineering and Technology, School of Engineering and Technology, Bharathidasan university, Trichy-620 024, Tamil Nadu,India.

Capparis sepiaria is a profusely branched hedge plant which is used as fodder for goats. The Literature review reveals that *Capparis sepiaria* was unexplored. With a view of identifying its medicinal properties and to unravel the facts scientifically, *Capparis sepiaria* was chosen for our study.The plant was collected in the Trichy District of Tamilnadu during June-July, dried under shade, powdered and extracted with ethanol as solvent, which was previously distilled. The chemical tests showed the presence of alkaloids, steroids, flavonoids, glycosides, amino acids and phenolic acid.A preliminary study to evaluate the antimicrobial activity of the crude ethanolic extract of *Capparis sepiaria* against Gram positive,Gram negative and fungi by agar disc diffusion method. The zone of inhibition was measured after the incubation periods of 24 hrs for bacteria and 48 hrs for fungi. The crude extract showed promising anti_microbial activity against Staphylococcus aureus, *β-haemolytic Streptococcus*, *Aspergillus fleavus* and *Acinetobacter Sp.* at 100mg/ disc.

CP 84 Wound healing activity of roots of *Eclipta alba* Linn.

M.B. Patil[1], S.S. Jalalpure[1], V.S. Nagoor[1], J.K. Saboji, S.M. Hishobkar, I. Vijaya Kumar, Shiv Kumar

K.L.E.S's College of Pharmacy, Nipani-591237 (Karnataka)

1. K.L.E.S's College of Pharmacy, Belgaum-590010 (Karnataka)

The ethanolic extract of Eclipta alba roots and its Petroleum ether, Solvent ether, ethyl acetate and butanol fractions were subjected to preliminary phytochemical investigation and screened for the possible wound healing activity by using incision, excision and dead space wound models in albino rats at the dose of 300 mg/kg orally.

Sterols, alkaloids, proteins, glycosides and tannins were found to be present in ethanolic extract and its various fractions. Treatment with ethanolic extract of *Eclipta alba* and its all fractions except butanolic fraction at the dose of 300 mg/kg produced significant increase in tensile strength of 10 day old incision wound, increase in wound closure rate and decrease in scar area and epithelization period of excision wound. There was also significant increase in granuloma breaking strength in dead space wound model, when compared to control group of animals.

The present study concludes that ethanolic extract and its petroleum ether, solvent ether, and ethyl acetate fractions of *Eclipta alba* roots possess significant wound healing activity. However, further tests are required to identify and isolate the group of active constituents responsible for its wound healing activity.

CP 85 Isolation of flavonoids from leaves of *Quisqualis indica* (Linn), family- Combretaceae

Nirmal Sunil*, S.C. Pal, P.S. Borhade, D.P. Belasare, M.S. Bagul

N.D.M. V.P.Samaj's College of Pharmacy, Gangapur Road, Nasik-2.

Quisqualis indica (Linn) family- Combretaceae is a large woody shrub, indigenous to tropical Africa and tropical Indo-Malaysian regions. It is cultivated in gardens throughout India up to an altitude of 300 m. It is commonly planted in gardens for its brightly colored, showy flowers. Fruits & seeds of Q. indica possess anthelmintic properties. It is also used in rickets of children. Leaves are used in compound decoction to relieve flatulence.

The leaves were collected and sun dried. It was powdered and subjected to successive extraction with petroleum ether (60-80° c), chloroform & methanol. Methanolic extract was dried & from it ethyl acetate soluble part is taken, that contain flavonoid compounds.

The compounds were separated by column chromatography. The isolated compounds were characterized by FTIR, U.V.shifting reagent technique, CO-TLC & melting point. Rutin, Quercetin & Quercetin-3-o-xyloside were isolated from methanolic extract.

CP 86 Antimicrobial activity of leaves of *Woodfordia fruticosa* Kurz, Family: Lythraceae

Sachin S*, Santhosh Kumar K, Pal S.C, Belsare D P.

*N.D.M.V.P.Samja's College of Pharmacy, Gangapur road, Nashik-2. E-mail: kshirasagar_mah@yahoo.co.in

Woodfordia fruticosa Kurz, Family: Lythraceae, is a small genus of arborescent plants. It is widely grown in Indonesia, Malaysia and India. In Sanskrit, it is well known as Dhatakipushpa. In Ayurvedic system of Medicine the dried flowers are used in the arishtas and asavas formulations to help fermentation. The aqueous extract of the plant causes the tonic contraction of the oestrogen-pretreated ulcers similar to oxytocin. The plant has been reported for their anti-HIV, anti-tumor, anti-inflammatory, antipyretic, immunomodulatory and sedative activities.

The leaves of *W.fruticosa* were not investigated phytochemically for antimicrobial activity. Methanolic and ethyl acetate extracts of leaves of *Woodfordia fruticosa* Kurz were tested for their antimicrobial and antifungal activities. The antimicrobial activity was determined on standard strains of bacteria *(E.coli, S.typhi, Klebisella pneumoniae, Proteus vulgaris, Staphyllococcus aureus* and *Bacillus subtilis)* and fungi *(Candida albicans* and *Aspergillus niger)*. The activity was found to be comparable with standard drugs such as ampicillin and cotrimoxazole for the antibacterial and antifungal activities, respectively. The ethyl acetate fraction has more antibacterial and antifungal activities than methanolic extract against standard bacteria and fungi.

CP 87 Evaluation of pharmacognostical characteristics of *Vitex negundo* Linn.

Krishna S*., Prachi M., and Mengi S.

NDMVP's College of Pharmacy, Shivajinagar, Gagapur Road, Nashik - 2

Vitex negundo Linn (Family Verbeneceae) commonly known as Nirgundi grows widely on

wastelands in India. The plant is mostly exploited for its insecticidal and repellent properties and also reported to possess number of medicinal properties besides wound healing activity. The plant was collected from the SNDT campus, Juhu, Mumbai, India. The leaves of the plant were evaluated with an aim to standardize the pharmacogonostical characteristics.

The fresh leaves were studied for histological and quantitative microscopical characteristics mainly stomatal number, stomatal index and palisade ratio. Dimensions and content per mg of covering trichomes and calcium oxalate crystal were established using powdered drug. Volatile oil content and physical constants and HPTLC fingerprints of volatile oil were also recorded.

The histological sections of plant revealed epidermal cells, collenchyma, palisade cells, mesophyll, xylem and phloem. The upper as well as lower epidermis showed the presence of covering as well as glandular trichomes and paracytic stomata. The pharmacognostical characteristics established were stomatal number; 111.73, stomatal index number; 4.45, palisade ratio; 4.38, length and breadth of covering trichomes 0.085 mm and 0.012 mm respectively, length and breadth of calcium oxalate crystal 0.029 mm and 0.019 mm respectively, number of trichomes and calcium oxalate crystals per mg of powder of leaves of plant 28702.29 and 102000 respectively. The volatile oil content of leaves of the plant was found to be 0.2%. The HPTLC fingerprint of volatile oil was obtained.

CP 88 Estrogenic and Uterine tonic activity of ethanolic root extract of *Musa paradisiaca*

Krishna Murthy G[1*], Prasad M.V.V[1], Ravada Ramesh[1], Jaiprakash B[2], Karadi R.V[2]

1. Dr. H.L.Thimmegowda College of Pharmacy, Kengal, Channaaptna
2. KLE's College of Pharmacy, JNMC Campus, Belgaum.

C.U. Shah College of Pharmacy, SNDT Women's University, Sir Vithaldas Vidya Vihar, Santacruz (W), Mumbai 400 049

Ethanolic root extract of *Musa paradisiaca* (Musaceae) was evaluated for its estrogenic activity using *in vivo* and *in vitro* experimental models. Estrogenic activity was studied in normal and ovariectomized rats. The extract was administered at a dose of 300 mg per kg.(per oral) for a period of 21 days. The parameters studied in both *in vivo* models includes changes in uterine weight, histometric changes of uterus. The effect was also studied on normal and regular estrous cycle. *In vitro* studies with extract on non-primed, estrogen- primed and extract pretreated uterus were carried out to find out whether it possess any oxytocin like activity. Administration of root extract in normal rats significantly increased the uterine weight, diameter of uterus, and thickness of endometrium. Extract treatment in ovariectomized rats did not show any change in uterine weight. The rats from both control and treated groups showed normal estrous cycle and produced significant contractile response on the non-primed, estrogen-primed and extract-pretreated rat uterus when exposed *in vitro*.

CP 89 Evaluation of psychopharmacological effects of some medicinal plants

Tamizh Mani.T*, Pulok K Mukherjee, Ramanathan.M, Subburaj.T, and Suresh.B.

Department of Pharmacognosy, JSS College of Pharmacy, Rockland's, Ooty 643 001

Valleriana wallichi belongs to the family Valerianaceae. It is used in indigenous system of medicine and for hypnotic, sedative, spasmolytic and central nervous depressant activity. *Vitex negundo* belongs to the family Verbenaceae. Leaves of the plant are used as an indigenous drug in different disease like rheumatic disease, headache, catarrhal fever and cervical spondylitis. *Withania somnifera* belongs to the family Solanaceae. The roots of *Withania somnifera* have been employed as a valuable drug in Ayurveda and Unani systems as a nervine tonic, as a sedative in the treatment of insanity, epilepsy and in certain forms of hypertension.The ethanolic extract of *Valeriana wallichi*, Vitex negundo and *Withania sonmifera* were evaluated for their psychopharmacological activities in several experimental models using Wistar albino rats. The extracts showed a significant reduction in Open field exploratory behavior pattern and increased immobility period. The extracts also showed a significant reduction in muscle relaxant activity by rotarod and significant reduction in locomotor activity. The extracts showed a remarkable increased in immobility period in porsolts swim test in the doses examined (50, 100, 200mg/kg). All the results were compared with respective controls for evaluation of significance. It indicates that these plant extracts having CNS depressant activity.

CP 90 Preparation and standardisation of phyto-pharmaceuticals meant for Viticulture (Grape science)

A.P.Pingle*, P.L.Gorde, M.D.Magar.

N.D.M.V.P.S's college of Pharmmacy, Gangapur Road, Nashik-2.

The requirement of today is a scientific approach to evaluate selected drugs among the

several hundreds of inorganic and organic drugs listed in ancient classics in different fields.Pharmaceutical drugs and formulations are used in viticulture as neutraceuticals or to control different dieseases in viticulture.

A new, simple, inorganic and organic compounds and their formulation have been developed for the fruit growth of grape.

Sulphates and nitrates of potassium, zinc, magnessium, ferrous and boric acids, citrates of potassium, mono ammonium phosphate, urea phosphtes are used to control deficiency symptoms of plants viz stalk necrosis, chlorasis, short and water berries, pink berries.

Different amino acids derived from beef and weed extract soyabean milk, neem cake, and polysaccharides, humic acids, vitamine B1,B2 and B6 permits full utilization of all biochemical and physiological reserves of the plants resulting in better yields in terms of both quality and quantity. The great plant was selected to study neutraceuticals in viticulture. Different formulations were made containing inorganic and organic pharmaceuticals to study physiological and biochemical role of above mentioned neutrients. Further more considering antibacterial activity of streptomycine , tetracycline, chloramphenicol and ampicillin can be used in combination to control different bacterial dieseases viz Anthraconose, black-rot. The formulation were evaluated with different parameters.

CP 91 Pharmacognostical and Preliminary Phytochemical studies on Leaves of *Spilanthes calva*

J. Anbu Jeba Sunilson[1], J. Rajeswari*, A. Thankatirupathi[1], S. Subaraj[2], N. Mahadevan[2]

S.B. College of Pharmacy, Sivakasi, Tamil Nadu, J.S.S. College of Pharmacy, Ooty, Tamil Nadu.

The present study includes the morphological and anatomical characters of the leaf along with the determination of Physico-chemical constituents such ash value, extractive value, crude fibre content, vein islet number and vein termination number. Phytochemical screening shows the presence of carbohydrate, glycosides, steroids and alkaloids in the petroleum ether, ethanol (95%) and aqueous extracts respectively. And volatile oil content determination of the leaf of spilanthes calva (fam: Asteraceae) to provide some pharmacognostical standards and serves as a standard reference for the identification of spilantescalva.

CP 92 Pharmacognostic and pharmacological studies on the stem bark of *Cordia obliqua* Willd

Bindhu A.R.. & M. Sukumar

S B College of Pharmacy, 3/77-C, Anaikuttam Road, Anaikuttam, Sivakasi 626 130

Literature reveals that different parts of the plant are widely used in traditional medicine for a variety of diseases. Bark specifically used as anthelmintic,in vitiated conditions of kapha, pitta, leprosy, as gargle in sore mouth, mild astringent, In general debility and convalescence. No reported work was done on the pharmacognostic and pharmacological study of bark.

The fresh bark of Cordia obliqua were collected from the foot hills of Ayyaaswami Malai, Ettimadai, Coimbatore and was identified by the Botanical Survey of India, Coimbatore. Detailed pharmacognostic studies were carried out on the bark of drug, revealing the anatomical characters and powder characters. Determination of dimensions of different cell types and tissue zones, ash values, extractive values and crude fibre content were carried out.

Antimicrobial activity - by Kirby Bauer method. Using *Staphylococcus aurens* for gram positive and Escherichia coli for gram-negative organisms. *Candida albicans* were used for the antifungal activity studies.

Free Radical Scavenging activity By DPPH Assay Method (Ascorbic acid as standard), Superoxide Radical Scavenging Activity by Nitro blue tetrazoline reduction method using dimethyl sulfoxamide (Thiourea as standard), Hydroxyl Radical Scavenging activity by Deoxy ribose assay method (Copper sulphate as standard), Lipid Peroxide Scavenging Activity by Thiobarbituric acid assay method (Vitamin E as standard).

Indian earthworm pheretima posthuma is used.5% gum acacia is used. Mebendazole suspension served as the standard & distilled water as control. The parameters recorded were the time taken for paralysis and time of death.

Anatomical Features, Analytical Parameters and Quantitative microscopy readings gave valuable reports which can identify the drug from related species and to determine the quality and purity of commercial samples. Antimicrobial activity studies showed that the benzene extract was having mild antibacterial and antifungal activity. Total ethanolic extract of the drug was found to have good free radical scavenging activity.Anthelmintic studies reveal that ethanolic extract is active in terms of producing paralysis at a concentration of 40mg/ml. Since no pharmacognostic studies were carried out, the values obtained here are useful in identifying the drug and thus determining the quality and purity of the drug. Pharmacological studies showed that the drug is having good free radical scavenging activity and anthelmintic activity in producing paralysis. It is also having mild antimicrobial activity.

CP 93 Further studies on the aerial parts of *Sphaeranthus amaranthoides* L.

B.N.Sinha*, P.Vipin Devi.Prasad and Abhishek Kumar**

Department of Pharmaceutical Sciences, Birla Institute of Technology, MESRA, Ranchi –835215

Dept. of Pharmasciences, M G University, Chiruvandoor, Ettunanoor, Kottayam

The present study has been carried out in addition to the work reported earlier on this plant. Anti-inflammatory activity using different phlogistic agents and antioxidant activity of the aqueous extract have been done on experimental animals. For evaluating the anti-inflammatory activity; Carrageenan, Histamine, Dextran, Formaldehyde induced oedema in rats were used. The effect produced by the aqueous extract on the exudation phase of inflammation, in aseptic arthritis model produced by different phlogistic agents, was evaluated. Percentage inhibition of oedema was calculated The extract was also studied for its antioxidant activity by screening the LPO (Lipid Per Oxidase) and SOD (Super Oxide Dismutase) level in the blood of the rats with oedema induced by carrageenan. The extract was found to possess both anti-inflammatory and antioxidant activities. Acute toxicity studies showed the extract to be safe up to a dose of 4000mg/Kg body weight .The required dose of the phlogistic agent was injected into the sub plantar region of the right hind paw of the rats to induce oedema .The paw volume was measured immediately after injection and at regular time intervals until the inflammation disappeared. The same was repeated for the aqueous extract at dose of 50, 100 and 150mg/ kg body wt. At the dose of 150mg/kg. body weight, aqueous extract has shown the best anti inflammatory and antioxidant activities which was comparable to the effect of Indomethacin (10 mg/kg. body weight).

CP 94 Pharmacognostical Representation of Various Parts of (Whole Plant) of *H. Marifolium Retz* (Boraginaceae)

R. Radha[1]*, P. Jayaraman[2], N.N. Rajendran[1]

1. Department of Pharmocognosy, Madras Medical College, Chennai.
2. P.A.R.C, Tambaram, Chennai.

Herbal remedies have been used for the treatment of various affections since time immemorial. The importance of herbal remedy was felt earlier possibly due to lake of scientific data and also due to advances in modern systems of medicines but due to prevails. Now at the global level the use of herbal formulation has increased and this that there exists a need have a check on the adulteration of the guanine drug with that of the specious one. Hence before subjecting the raw (Plant) material to the pharmaceutical process, it has to be authenticated by its macro and micro scopical characters, so an attempt was made to study the anatomical characters of the various parts of the plant (Stem, Root, Leaf) H. Marifolium Retz

The plant specimen collected and the different organs were cut and removed from the plant and fixed in tAA. The paraffin empdded specimens sectioned with the help of Rotary Microtom. The sections were stained with Toluidine blue. Stomatal Morphology, Venation pattern and trichome distribution, paradermal sections were also done by leaf pealing. Microscopic description of tissues are supplemented with Micro graphs wherever necessary. Photographs of different magnification were taken with Nikon Lab phot 2. Microscopic unit.

Interestingly the photo micrographs indicated the significant characters of the plant to be

- Unicellular, thickwalled rough boraginaceous type ofepidermal trichomes.
- Rosette of epidermal cells forming a sheath around the base of trichome, each cell bearing cystolith-like bodies.
- Isobilateral leaf with district Kranz – tissue
- Boat – shaped petiole with simple arc of collateral vascular strand.
- Typical dicotedonus type of leaf stems and root anatomy.

A comparative anatomy of the allied specious of the plant may be undertaken to facilitate its substitution for the genus H. Marifolium Retz

CP 95 Pharmacognostic evaluation of Ratanjot-*Arnebia nobilis* Rech.f.

Sayyada Kharoon*, B.N. Mehrotra and Shanta Mehrotra

Pharmacognosy and Ethnopharmacology Division, National Botanical Research Institute, Lucknow 226 001

Ratanjot is attributed to 8 various boraginaceous species belonging to the genus *Alkanna*, *Arnebia*, *Maharanga* and *Onosma* and regarded as one of the important herbal drugs of indigenous systems of medicine. The root and root stock, which forms the actual drug, is considered to be an anthelmintic, antipyretic, antiseptic and claimed to be useful in burn, eczema, wounds and eruptions and are also used for treating the diseases of eyes, bronchitis, abdominal pains and itch etc. Several workers reported that the Naphthaquinones (arnebins), the main active

constitutents of the drug are responsible for its colour and therapeutic efficacy. Professor Bole (1961, 62) described that the *Arnebia nobilis* is the genuine Ratanjot and is imported to India from Afghanistan but during the course of botanical survey of Himalayan region, was found that the red coloured roots resembling with *A. nobilis* were gathered by local people for commercial purposes. Hence, it is decided to evaluate *Arnebia nobilis* pharmacognostically.

The present study revealed that *Arnebia nobilis* can easily be distinguished from other boraginaceous roots by macro-microscopic, SEM characters and presence of different arnebins. Roots of this plant are 1-5 cm broad and T.S. showed outermost xylem with broad vessels and innermost with groups of radially arranged narrow vessels while the middle region occupied by alternate rings of clusters of broad and narrow vessels. Parenchymatous pith is also present. The scanning electron microscopic studies of radical leaves showed broad hairs with saucer shaped bases and warty blocks on the surface which gradually disappearing and forming finely ridged surface towards the apex. The TLC finger print profile provides arnebins-1 and 3-7 along with additional components at Rf. 0.32, 0.45, 0.85, 0.92 and arnebin-2 is absent.

CP 96 Anti-Inflammatory activity of *Redia floribunda*

G. Vijaya, B. Narasimha Naik, K.G.G.M.B.G. Tilak, S. Bala Gayatri, K. Hemamalini M. Vimal Kumar Varma.

Smt. Sarojini Ramulamma College of Pharmacy, Mahabubnagar, Andhra Pradesh.

Redia floribunda is available in the station of Koili hills in Tamilnadu and used in the treatment of skin diseases including Psoriasis, and also used in wound healer's and allay pain. Phyto chemical test have indicated the presence of Flavanoglycosides, and steroidal glycosides, and on screening we have recently gained considerable eminence as a result of their anti-inflammatory & anti-arthritic actions.

The methanolic extract of *Redia floribunda* was studied for its anti-inflammatory activity given by intraperitonial route, the extract inhibited in a dose dependent way carrageenin induced paw-edema in rats and egg white induced hind paw edema, the calculated LD50 was 150mg/kg body weight and Indomethacin was used as a standard drug at the close of 10mg/kg.

CP 98 Termiticidal Compounds of *Diospyros assimilis*

S. Ganapaty[a], P.Steve Thomas [a], Gloria Karagianis and Peter. G. Waterman [b]

a. Pharmacognosy and Phytochemistry Division, Department of Pharmaceutical Sciences, Andhra University, Visakhapatnam - 530003.

b. Centre for Phytochemistry, Southern Cross University, Lismore, P.0.box.157, NSW 2480, Australia.

Diospyros assimilis Bedd. Fam: *Ebenaceae,* also known as the royal timber is regarded in India as one of the major ebony bearing trees. The genus *Diospyros* consists of woody shrubs and trees distributed in the tropical and sub-tropical regions of the world. Around 500 species are known world wide of which, 24 species are native to India. The *Diospyros* species are used as herbal remedies for the treatment of whooping cough, leprosy, dysentery, menstrual troubles and abdominal pains. The antibacterial, antifungal and termite resistant properties of the genus Diospyros have all been attributed to the presence of naphthoquinones. *D. assimilis,* a species available locally was chemically examined for its constituents and also for the termiticidal activity as the plant was not studied earlier. The results are reported hereunder.

The roots of *D. assimilis* (1.6 kg) were extracted with chloroform. The toxic effects of the root extract of

D. assimilis at dose levels of 50 mg (10%), 2 mg (2%), and 1 mg (1%) were studied for 48 h against the survival time of *Odontotermes obesus Rambur* workers on forced direct exposure in a No-choice situation. The root extract at 1, 2 and 50 mg concentrations resulted in 100% mortality of termite workers in 48 h.

Phytochemical examination of the extract afforded a novel naphthaldehyde identified as 4-hydroxy-3, 5-dimethoxy-2-naphthaldehyde, two isomeric â-naphthaldehyes and three known naphthoquinones namely plumbagin, diospyrin and hydroxyisodiospyrin. The compounds were tested at 10 mg concentration and showed promising termiticidal activity on exposure to O.obesus workers for 24, 48, 72 and 96 h and for up to a week.

The present study revealed that 4-Hydroxy-5-methoxy-2-naphthaldehye showed the highest mortality rate of 100% to O.obesus workers within 24 h while plumbagin exhibited a mortality rate of 100% in 36 h. 4-hydroxy-3, 5-dimethoxy-2-naphthaldehyde and isodiospyrin showed 100% mortality in 48 and 72 h respectively and diospyrin produced 100% mortality after nearly a week. From the above findings, the major termiticidal components identified were 4-Hydroxy-5-methoxy-2-naphthaldehyde, plumbagin, 4-Hydroxy-3,5-dimethoxy-2-naphthaldehyde and Hydroxyisodiospyrin while diospyrin was less toxic to *O.obesus* termite workers at the concentrations tested.

DP$_1$ Herbal plants used in the treatment of mouth ulcer

N.H. Indurwade, A.A. Mendhe*, P.N. Gurjar, N.V. Janbandhu

S.N. Institute of Pharmacy, Pusad-445 204, Dist. Yavatmal (M.S.)

Mouth ulcer is a very common disease seen in the different population and frequently observed or which affected people seek treatment. The attempts made for the treatment of mouth ulcer are very less.

Many doses forms are available in the market used for the treatment of mouth ulcer. The drug Choline salicylate are used popularly for the treatment of mouth ulcer but, it may appears few side effects such as gastrointestinal irritation, dizziness, headache etc.

Hence, most of the potent herbal drugs used in the treatment of mouth ulcer are available and having negligible side effects. From ancient period, people are used in herbal plants as a home remedies for the mouth ulcer treatment, e.g. honey, ghee, butter is applied to the affected part frequently. The main advantage of using herbal drug is that, it is safer than synthetic drugs and hence even it is swallowed accidentally, the risk of systemic side effects is less.

The marketed preparations have been used in very few number of herbal drugs e.g. gulvel, durva, karanja, jasmine, Glycerrhiza, gunja, bor, ranshevari, etc. have antibacterial, anti-inflammatory, analgesic, cooling effect, astringent activity either singly or collectively. So, the use of herbal drugs instead of synthetic drugs will make the formulation more effective and safer. All of the herbal drugs discussed here have exhibited significant clinical and pharmacological activity and potency.

DP$_2$ Sedative and analgesic activities of the petroleum ether extract of *Cuscuta reflexa* Roxb. stem in mice

Dilipkumar Pal , Chinmoy Panda, Arnab Dutta, Samir Sinha Babu and Dipankar Laha*

Seemanta Institute of Pharmaceutical Sciences, Jharpokharia, Mayurbhanj-757 086,Orissa.

The use of plant preparations and medicaments for various diseases started from the ancient period of time. Folk medicine provides a valuable approach in the search for development of new and useful therapeutic agents. *Cuscuta reflexa* Roxb. (Swarnalata in Bengali, Nirmuli in Oriya, family *Convolvulaceae*) stem, a tribal medicine for the diseases like fits, melancholy, insanity, pains in the muscles & the joints, is taken for our present study to investigate the sedative and analgesic activities of the petroleum ether extract of C. reflexa stem (PECR) on albino mice.

Powdered stems of *C. reflexa* was extracted with petroleum ether (40°-60°), evaporated to complete dryness and dissolved in arachis oil (vehicle) for pharmacological studies.The LD_{50} value of PECR is 700 mg/kg, i.p. PECR in low, medium and high dose level lengthened significantly the sleeping time induced by standard sedatives in the order: Sodium pentobarbitone,105%, 224%, 342%; Diazepam 115%, 190%, 280%; meprobamate 117%, 208%, 286% compared with vehicle (arachis oil) control mice. PECR significantly reduced the number of writhes and stretches induced in mice by acetic acid 1.2% solution, with a dose of 150 mg/kg,i.p.,the percentage protection being 50%.This dose dependent effect reached 72% with a dose of 250 mg/kg, i.p.

The prolongotion of sleeping time by PECR may be due to CNS depressant action or due to enhancement of GABA-ergic transmission.The profound analgesia produced by PECR may be related to the increased brain serotonin level in mice. All these studies indicate that the petroleum ether extract of C. reflexa stem posseses CNS depressant action. However, more extensive studies are required to understand the mechanism of drug action and the chemical nature responsible for it.

DP$_3$ Preliminary antimicrobial activity of some traditional antiacne plants

Sumitra Singh, S.K. Sharma, M.P. Singh

Dept. of Pharmaceutical Sciences, (Pharmacognosy and Phytochemistry Division), Guru Jambheshwar University, Hisar 125 001

Acne is a disease which affects more than 90% of young people, which leads to permanant marking of the skin, disfiguring of the face. Several factors involved in the pathogenesis of acne, such as sebum, inflammation, abnormal folicular differentiation and various bacterial. Several plants have been traditionally used to treat acne; however, their effectiveness has not been tested in scientific way. It was, therefore, decided to prepare ethanolic and aqueous extracts of some traditional antiacne plants by soxhlet extraction. The extracts were tested for preliminary antimicrobial studies. Further works regarding phytochemical studies, development of suitable formulation, standardisation and antimicrobial activity of other plants under way.

DP$_4$ Glucose Lowering Effect of Polyherbal Formulation in Normal and Diabetic Animals

T.Subburaju, A.Sutharsan, Sheeba Babu*, B.Suresh.

J.S.S.College of Pharmacy, Department of Pharmacognosy, "Rocklands", Ootacamund-1, Tamilnadu.

A better therapeutic efficacy at low doses, stability and bioavailability are the reported advantages of polyherbal formulation. A polyherbal formulation containing *Gymnema sylvestre* (Asclepiadaceae), *Syzygium cumini* (Myrtaceae), *Helicteres isora* (Sterculiaceae), *Casearia esculenta* (Samydaceae) was developed based on the individual plants activity. The presence of phytoconstituents on individual plant extracts were confirmed by HPTLC and spectral methods. The preliminary phytochemical studies of the formulations were carried out by chemical, HPTLC and spectral methods. The glucose lowering activity of polyherbal formulation in normal and alloxan induced diabetic rats were evaluated for euglycemic effect, oral glucose tolerance test, single dose study and multidose study on diabetic rats at 150mg/kg and 300mg/kg. The glucose lowering activity of polyherbal formulation in normal rats showed a decrease of 29.62% at 150mg/kg and 47.12% at 300mg/kg at 2 hr(Phenformin 52.17%, Glibenclamide 39.4%). The oral glucose tolerance test showed a decrease in blood glucose by 9.02% at 150mg/kg and 12.5% at 300 mg/Kg at 4hr (Glibenclamide 8.70%, Phenformin 13.82%). The single dose study in diabetic rats showed a decrease in blood glucose by 46.82% at 150 mg/kg and 52.59% at 300mg/kg at 2hr (Glibenclamide 53.83%, Phenformin 50.87%). In the multidose study, the oral administration of the formulation for 21 days twice daily showed a decrease in blood glucose by 62.01% at 150mg/kg and 70.49% at 300mg/kg at the end of 21 days (Phenformin 66.88%, Glibenclamide71.9%). Biochemical estimation revealed no marked alteration in levels in formulation treated animals. This study confirmed the antidiabetic effect of the polyherbal formulation in various models.

DP$_5$ Evaluation of aqueous Umbelliferous fruit extracts for nootropic activity using conditioned avoidance responce (Car) in rats

S. Satyanarayana, B. Krishna Murthy, N. Srinivas, K. Sushruta*

Dept. of Pharmaceutical Sciences, Andhra University, Visakhapatnam

Nootropics are drugs which enhance the cognitive functions. In man learning consists of acquiring information about what lead to what and memory is the capability of recalling the acquired information atleast once and usually again and again. The objective of our study is to evaluate the aqueous umbelliferous fruit extracts for nootropic activity using conditioned avoidance response in rats.

Albino rats of either sex weighing 150-200 gm were used in the study. Rats were divided into 4 groups, each containing 5 animals. All the groups of rats were trained for CAR by using Cook's pole Climbing apparatus. Group-I, Group-II and Group-III received 100, 200 and 300mg/kg body weight oral doses of caraway (CA) extract respectively. Group-IV received distilled water and was considered as control group. After 90 minutes all the four groups were subjected to the training schedule as described below.

Each rat was placed in a Perspex chamber and it was left there for about 5 minutes to allow it to get accustomed to the chamber. Five minutes later the buzzer was given followed by the shock through the grid floor. The rat had to jump on the pole to avoid foot shock. Jumping on to the pole functionally terminates and this was classified as an escape while such jumping prior to the onset of the shock was considered as avoidance. Shock was terminated on the floor of the chamber. After jumping on to the "pole" an interval of 20-30 seconds was given before the next trial sequence. The session was terminated after 60 trials were completed. This procedure was repeated at 24 hours interval until each subject (animal) reaches 95-99% avoidance. After complete training of the groups, the animals were treated with scopolamine butyl bromide (1mg/kg body weight IP). After 30 minutes of scopolamine treatment, the groups were treated with oral doses of extract / distilled water and after 90 minutes they were tested for CAR. The schedule was continued with daily doses of extracts and vehicle until they return to normal level from scopolamine induced amnesia. Similarly the other extracts of cumin (CU), coriander (CO), dill (DI) and fennel (FE) were also evaluated.

The percentage of avoidance was always higher in all extract treated groups compared to the vehicle treated matching control. The amnesia produced by scopolamine was less in caraway and other extracts treated groups compared to control. The order of nootropic activity was CA>DI>CU^{3}CO>FE.

In separate *in vitro* and *in vivo* studies it was found that the extracts possess strong antioxidant activity and it may be responsible for the nootropic activity partly. Since scopolamine amnesia was found to be less in the presence of extracts, cholinergic muscarinic action may also be involved. Work on the involvement of other mechanisms is in progress.

DP 6 Estimation of ascorbic acid in static and suspension cultures of *Convolvulus microphyllus* Sieb.

R. Zafar, Sayeed Ahmad and Mohd. Mujeeb*

Plant tissue culture laboratory, Department of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi 110062

Convolvulus microphyllus Sieb is a very important medicinal plant, used in Indian system of medicine for enhancing the memory in the name of Shankhpushpi.

Callus cultures of leaf and stem explants has been initiated and maintained successfully on MS basal medium supplemented with 2,4 dichlorophenoxy acetic acid (2,4-D), 6- benzyl adenine (6-BA), Indole acetic acid (IAA), and Kinetin (Kin) each having concentration of one parts per million. The best cell lines of leaf callus were used for the development of cell suspension culture on the MS medium supplemented with same growth hormone excluding agar.

The natural leaf, stem their respective calli and cells of suspension culture were examined chemically for different secondary plant metabolites. The ascorbic acid a potent antioxidant compound was found to be present in natural plant as well as in culture extracts for the first time.

The ascorbic acid was estimated quantitatively by UV spectrophotometric method at 650 nm using reference standard and the amount of ascorbic acid in natural leaf and stem was found 0.342 % and 0.340 % while incase of leaf callus, stem callus and in suspension culture it was found 0.080 %, 0.079% and 0.241% w/w respectively.

The results obtained in present investigation reveals that the *in vitro* culture system can be used as an alternative source for the production of secondary metabolites present in natural plant.

DP 7 Biomarker profiling for *Phyllanthus amarus* – New tool for standardization of botanicals

Pulok K. Mukherjee*, A. Wahile , K. Mukherjee, B. P. Saha, M. Pal, S. Rai, K.H.F. Nazeer Ahmed, K. Maiti, S. Raja, A. Gantait, V. Kumar

Natural Product Studies Laboratory, Dept. of Pharm. Technology, Jadavpur University, Kolkata 700 032

Identification and quality evaluation of crude drugs is a fundamental requirement of Industry and other organizations dealing with Ayurvedic and herbal products. The fact must be taken into account that the plant material to be examined has a complex and inconsistent compositions based on its contents of secondary metabolites. Therefore the analytical limits are not as precise as for the single chemical entity. Adequate standards using biological, chemical, instrumental and physiochemical methods required to be developed.

Based on experience attempts have been made here to come up with monograph using WHO protocols, on Phyllanthus amarus. In India, the plant is often used in traditional system of medicine for a variety of ailments including flu, dropsy, diabetes, jaundice, asthma, bronchial infections, and diseases of the liver. In Ayurvedic system of medicine it is used in problems of stomach, genito-urinary system, liver and kidney. Marker analysis of this plant extracts were made with high performance thin layer chromatography (HPTLC) method with the suitable solvent system and scanned at 254nm wave length. The major bioactive lignan constituents of the plants Phyllanthin and Hypophyllanthin, have been used as standard to compare various extracts of the plant. Other parameters like test for extraneous material, physico-chemical analysis based on the WHO protocol were performed. While successive extractive values and phytochemical analysis for the quantification of standards was carried out by HPLC with in house standard plant material. HPTLC chromatograms were developed for various extracts of Phyllanthus amarus. The R_f values in Hexane : Ethyl acetate (2:1) were 0.3 and 0.4 for Phyllanthin and Hypophyllanthin respectively.

We are thankful to All India Council for Technical Education (AICTE), New Delhi for the necessary financial assistance.

DP 8 Development of fingerprint of *Hemidesmus indicus* RBr. Using reverse phase - high performance liquid chromatography

R.T.Sane, S.N. Menon, Aditi Bhugra*, Archana Thokale ,Neeta Kadam**

Therapeutic Drug Monitoring Lab., 194, Scheme No. 6, Road No. 15, Sion (East), Mumbai 400 022.

Plant materials and herbal remedies derived from them represent substantial portion of the global market and in this respect internationally recognized guidelines for their quality assessment and quality control are necessary. WHO has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable standards. Herbal drugs are a diverse range of botanical materials including leaves, herbs, roots, flowers, seeds, inner bark, etc. A comprehensive specification must be developed for each drug even if the starting material for the manufacture of the finished

product is a herbal preparation. The specification should be established on the basis of recent scientific data. For the current work an HPLC method for the fingerprinting of the root, leaf and stem of *Hemidesmus indicus R.Br.* (family Asclepidiaceae), which is used by Folk healers and in Ayurveda for treatment of kidney disorders was developed. From the results obtained it is clear that the method is specific for *Hemidesmus indicus*. The method is also precise and it could detect upto a concentration of 10mg/ml.

DP$_9$ Rapid screening method for determining antioxidant activity of herbal formulations using HPLC

D. Chandrasekar*, S. Ramakrishna and P.V. Diwan

Pharmacology Division, Indian Institute of Chemical Technology, Uppal Road, Hyderabad – 500 007, India

Herbal formulations are available in the market for antioxidant and hepatoprotective activity. The conventional DPPH colorimetric method of screening free radical scavenging activity is limited to colored substances due to interference from pigments. A reversed – phase HPLC method was developed to detect the DPPH radical. Detection was carried out at 517 nm using a mobile phase of acetonitrile : water (80:20, v/v) at a flow rate of 1 ml/min. The difference in the reduction of DPPH peak area between a blank and the sample was used for determining the percent racial scavenging activity of the sample. DPPH gave a sharp peak at a retention time of 6.24 min with no interferences. The method was standardized using known antioxidants Ascorbic acid, Trolox, Probucol and a-Tocopherol (IC_{50} 46.11±4.78, 67.78±3.78, 52.66±2.59, 63.57±0.67 mM respectively, n=3). The linearity of Trolox was good over the concentration range of 20 to 100 M (correlation coefficient, r2 = 0.99). The reproducibility of the DPPH peak area was good with an intra-day coefficient of variation (%CV) of 8.97 and inter-day %CV ranging from 7.49 to 8.30 (n=6, each run). This method was successfully applied for the estimation of free radical scavenging activity of Silymarin and few commercial hepatoprotective herbal formulations (Liv.52â New LiveFitâ, Livinaâ and Livomynâ) as a process of rapid screening methodology. The HPLC method was specific and can be used for the rapid determination of free radical scavenging activity of variety of products including plant extracts, foods, drugs and colored formulations.

DP$_{10}$ Effect of topically applied botanical extracts on regeneration and barrier properties of human skin

Shailendra Gurav*, S. S. Pandit, P. Meghal and C. L. Lakhotiya.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur-440 033.

The present study was carried out to assess the skin regeneration and skin barrier properties of topically applied botanical extracts (phyto-pharamceuticals or herbals).

Based on traditional knowledge and experience three botanicals mentioned in Indian System of Medicine were selected for the study. These are Ficus religiosa, Rubia cordifolia, Curcuma longa .

Above botanical extracts were prepared by cold maceration with ethanol : water (1:1) at room temperature for 15 days. Dispersion of botanical extract in propylene glycol were prepared and applied to volar forearm of human volunteers.

To assess skin regeneration activity, time required to decline the fluorescent intensity of Dansyl chloride (a fluorescent marker) treated with botanicals is measured till the fluorescens completely disappeared.

The skin barrier properties assesed by measuring biophysical parameters like moisture content, skin sebum and skin pH before and after 1,3 and 5 hours of application by sebumeter-corneometer-pH meter combination unit.

The maximum skin regeneration activity was shown by extract of *Curcuma longa* followed by, *Rubia cordifolia* and *Ficus religiosa*.

In case of skin barrier properties, skin showed no alteration in moisture content while sebum content was decreased and acidity of skin further increased.

DP$_{11}$ Hepatoprotective activity of *Momordica charantia* leaf juice in alcohol and Carbon tetrachloride(CCl_4) treated rabbits

S.Satyanarayana,D.Srinivasa Raju,T.Kalpana*

Dept.of Pharm.Sciences, Andhra University, Visakhapatnam-530003.

The use of *M.charantia* fruit juice and leaf juice for the treatment of diabetes is well known and has been scientifically established. The same is also used for the treatment of jaundice by several ayurvedic physicians and some allopathic doctors without

scientific evidence. The present study is a preliminary study on its usefulness in jaundice. The objective of our study is to evaluate the *Momordica charantia* (Bitter gourd) fresh leaf juice/vacuum dried powder for hepatoprotective activity against alcohol and CCl_4 treatment induced damage in rabbits.

Adult albino rabbits of either sex weighing 1.5-2.5 Kg were divided into 5 groups. First 3 groups containing 3 animals each were used for establishment of prophylactic action. Group IV & V containing 2 animals each were used for establishing curative action. Group-I served as a control. Group-II & group-IV served as a treated control for prophylactic and curative activity respectively. Group-II & group-IV received alcohol 40% (1ml/100gm body weight, oral) for 21 days in the evening and on 20th day received CCl_4 in olive oil (1:1 ratio) intraperitoneally. Group-III received 1 ml of diluted *M.charantia* fresh leaf juice in the morning in addition to the above. Group-V received 3 ml of *M.charantia* fresh leaf juice in the mornings from 21st-31st days and were also given the alcohol (21 days) & CCl_4 (20th day) treatment in the evenings. The blood samples were withdrawn from prophylactic group on 0th,7th, 15th,& 21st days and on 0th,12th,25th&31st days from curative group from marginal ear vein and were analysed for SGPT(Serum Glutamate Pyruvate Transaminase), SGOT(Serum Glutamate Oxaloacetate Transaminase) & ALP(Alkaline Phosphatase) using standard procedures.

Alcohol & CCl_4 treatment produced a significant increase in serum SGPT, SGOT &ALP levels by21st day in prophylactic control compared to their basal levels. This rise in SGPT, SGOT &ALP was reduced with concomitantly given 1 ml diluted *M.charantia* fresh leaf juice indicating prophylactic action. In matching controls for curative treatment group SGPT, SGOT & ALP levels were increased by 21st day and continued up to 31st day. The curative treatment with 3 ml *M.charantia* leaf juice reduced the rise of SGPT, SGOT & ALP levels by 31st day i.e. after the hepatic insult with alcohol and CCl_4 indicating curative action. Vacuum dried powder of leaf juice given after hepatic damage (tested for curative activity similarly) also produced curative activity but it was relatively less compared to fresh juice. The clinical study conducted separately on jaundice patients with 3 ml of *M.charantia* leaf juice given for 4 days significantly reduced the serum bilirubin levels and showed the absence of bile salts and bile pigments in urine confirming hepatoprotective activity of the leaf juice and its usefulness in humans.

DP$_{12}$ Hepatoprotective and free radical scavenging activity of *Terminelia belerica.*

Patel N.M.[1], Patel P.M.[2], Patel V.P.[1], Patel J.L.K. Pundrikakshudu[3] & Bhavsar G.C.[3]

B.M. Shah College of Pharmacy, College Campus, Modasa, Dist. Sabarkantha, Gujat 383 315

Terminelia belerica (Combretaceae) is claim as the medical potential in Ayurveda. Hence it was included in our scheme of investigations for antihepatotoxic and antioxidant activities. Generation of excess of peroxidase enzymes, which produce free radicals and trigger a cascading reaction. Hence it was felt rather logical to correlate the antihepatotoxic activity with antioxidant activity.

Methanolic extracts of *Terminelia belerica* were studied in CCl_4 induced hepatic damage in rate. Silymarin (25 mg/kg) was used as reference standard. Significant change in SGOT, SGPT, ALP, bilirubin and total protein level were measured. Histopathology was carried out for confirmation, antioxidant activity was studied by DPPH, nitric oxide scavenging and super oxide methods.

The reduction in the level of SGOT, SGPT and ALP after administration of methanolic extract of *T. belerica* (300mg/kg) was significant. EC_{50} values were find out for DPPH, Nitric oxide scavenging and super oxide methods. These results show *C. procera* having hepatoprotective and antioxidant activity. The results were confirmed by histopathological study.

DP$_{13}$ Development of mono ingredient herbal neuroleptic tablet for better *Psychiatric therapy*

Samanta, M.K, Wesley, N.E.S*, Anil Chand, B., Mahadevan, N., Wagh Vijay, D. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu- 643001.

Conventional synthetic antipsychotic drugs used for the treatment of psychosis are associated with self-induced extrapyramidal side effects. Herbal neuroleptic tablets using three drugs namely Acorus calamus (I), *Glycyrrhiza glabra* (II) and *Withania somnifera* (III) individually and in combination were formulated, standardized and evaluated .These herbal drugs are expected to be devoid of these side effects. Wet granulation technique was employed for tablet formulation and simple aqueous based coating was done by spraying of the moving bed of compressed tablets (HPMC 6%, 15cp). The compressed tablets after coating were then subjected for various physical evaluations. The qualitative and quantitative estimation of various active constituents was done by

HPTLC from the herbal tablet. The HPTLC elution media is Toluene: Ethyl acetate (93:7) for I, Methanol: Strong ammonia (200:3) for II and Ethyl acetate: Ethanol: Water: Ammonia (65:25:9:1) for III were used. 2.81mg of Beta-asarone, 2.95mg of glycyrrhizic acid and 0.69mgof withaferin-A were found. Tranquillizing effect, anxiolytic efficacy and catatonic response were measured in albino rats. An optimum therapeutic efficacy was confirmed by tranquillizing effects ($P<0.001$) using rotarod method and anxiolytic effects by thiopental induced sleeping time on albino rat model. No drug induced catatonia (Score=0) was observed with the developed herbal tablet formulations in the rat model. The results indicated that mono ingredient herbal neuroleptic tablet dosage form posses no catatonic side effects, indicating a better alternative to synthetic drugs for long term psychiatric therapy.

DP 14 Evaluation of anti-depressant and antistress activity of Cystisus *scoparius Link* and *Andrographis paniculata* Nees in Wistar Rats

Nirmal J*, Saravana Babu C, Harisudan T, Jayadev S, Ramanathan M and Suresh B.

J.S.S College of Pharmacy, Rocklands, PB. NO:20, Ootacamund - 643001, Tamil Nadu.

The present study was planned to evaluate the antidepressant effect of *Cystisus scoparius* Link and *Andrographis paniculata* Ness in mild chronic unpredictable stress induced depression. The depression was induced by following the method of Pal and Dandya. The antidepressant effect of the herbs was evaluated by using behavioural despair test and locomotor activity evaluation, the data were also supported by biochemical measurements. The *Cystisus scoparius* Link and *Andrographis paniculata* Ness were air dried and extracted with 60% methanol followed by vacuum drying and kept in the desicator. *Cystisus scoparius* and *Andrographis paniculata* were standardized to its phenolic content using Follin-Ciocalteau method and the percentage was found to be 3.64±0.16 and 8.54±0.16 respectively. Twenty one days administration of stress resulted in depression as indicated by decreased body weight, aggressive behaviour and increased immobility period in Porsolt's swim test. Blood glucose, protein level and ulcer scores were also found to be altered with stress. Treatment of *Cystisus scoparius* (250mg/kg) and *Andrographis paniculata* (200mg/kg) standardized methanolic extract significantly reversed the stressed induced depression. In comparison to *Andrographis paniculata*, *Cystisus scoparius* produced significantly better anti-depressant activity. It can be concluded that standardized *Cystisus scoparius* and *Andrographis paniculata* have antidepressant property.

DP 15 Comparative study of anti-oxidant activity of barks of *Terminalia arjuna* Roxb. and *Saraca asoca* Roxb

Sunita Hedaoo*, Sarita Karthikeyan, N.D.Grampurohit

C.U.Shah College Of Pharmacy, S.N,D,T,Women's University,Santacruz (west), Mumbai.

Free radicals are produced continuously in the human body during metabolism, which play important role in the initiation and promotion of degenerative diseases. Arjuna bark obtained from *Terminalia arjuna* Roxb. (Combretaceae) and Ashoka bark obtained from Saraca asoca Roxb.(Caesalpiniaceae) are used extensively in indigenous systems of medicine mainly as cardiotonic and uterine tonic respectively. Antioxidant activity of both the barks has been studied.The total aqueous and methanolic extract of Ashoka bark has shown very good antioxidant activity when tested in our labrotary. The antioxidant activity of Arjuna bark is reported in literature. Both these plants have shown promising activity and contain tannin as their major constituent (15% in Arjuna and 6% in Ashoka). As tannins are proved antioxidants the aim of this study was to trace the non-tannin constituents, which may be responsible for antioxidant potential.

For extraction of tannins aqueous (Aq) and hydroalcoholic(Ha) extracts were prepared. The tannin and non-tannin parts were separated by Stass-Otto method by using 10%lead acetate and H_2S. Further Ashoka bark was successively extracted with pet ether and absolute alcohol. Total absolute alcoholic extract was further fractionated with chloroform, n-butanol, absolute alcohol, and 95% ethanol. Total extracts, tannin and non-tannin fractions were tested for antioxidant activity by DPPH method using ascorbic acid as a standard. IC_{50} values were calculated for comparison and chemical nature of the constituents were identified by TLC and chemical tests.

The IC_{50} values of total Ha and Aq extract of Arjuna bark were 3.5 µg/ml and 9.9 µg/ml resp.

The IC_{50} values of Ha and Aq tannins were 2.3µg/ml and 17µg/ml resp whereas Ha and Aq non-tannins were 305µg/ml and 430µg/ml resp

The IC_{50} values of total Ha and Aq extract of Ashoka bark were 4.5µg/ml and 13.5µg/ml resp

The IC_{50} values of Ha and Aq tannins were 1.7µg/ml and 35µg/ml resp, whereas Ha and Aq non-tannins were 640µg/ml and 300µg/ml resp.

From the result it is proved that the activity is mainly attributed to tannins. The non-tannin fractions of *Terminalia arjuna* were identified as saponins by TLC. Amongst the different fractions of Ashoka bark tested absolute alcoholic and chloroform fractions showed best activity, which were identified as tannins and anthocyanin pigments respectively.

DP 16 In-vitro antioxidant effect of whole plant extracts of *Scoparia dulcis* L.

Rema Razdan, Praveen T.K., Nilesh patel*

Dept. of Pharmacology, Visveswarapura Institute of Pharma Science, 24th Main Road, 25th Cross, KIMB Building, BSK II Stage, Bangalore 560 070

Scoparia dulcis L. (family: Scrophulariaceae) a medicinal herb distributed throughout India, contains hexacosonol, â-sitosterol, D- mannitol, flavonoid, 7-o-methyl scutellarein and glutinol. In addition it also contains alkaloids, di and triterpenoids.

In an attempt to assess the possible antioxidant activity of aqueous and alcoholic extracts of Scoparia dulcis L. 3-in vitro assays, namely NO scavenging, DPPH scavenging and reducing power assays were conducted. The IC_{50} values of aqueous extract for NO scavenging, DPPH scavenging and reducing power assay was found to be 556.7µg/ml ± 3.3 (mean ± SEM), 366.7 µg / ml ± 17.6 (mean ± SEM) and 90.0 µg / ml ± 0.0 (mean ± SEM) respectively. The IC_{50} values of alcoholic extract for NO scavenging, DPPH scavenging and reducing power assay was found to be 626.7µg/ml ± 42.9 (mean ± SEM), 370.0 µg / ml ± 7.6 (mean ± SEM) and 118.3 µg / ml ± 5.4 (mean ± SEM) respectively. Silymarin used as standard, showed potent scavenging activity with IC_{50} values 49.7µg/ml ± 0.9 (mean ± SEM), 281.7 µg / ml ± 19.2 (mean ± SEM) and 17.7 µg / ml ± 0.3 (mean ± SEM) respectively for NO scavenging, DPPH scavenging and reducing power assay.

The results obtained from the above study clearly suggest that both aqueous and alcoholic extracts of *Scoparia dulcis* have reducing power and free radical scavenging abilities. The aqueous extract exhibited the most significant activity.

DP 17 Evaluation of traditional herbal formulation for adaptogenic activity

Md.Jameel Patel*, Roshan.S, Savadi R.V. Saleem M.A., Sadath Ali, Sanaullah.S,

Luqman College of Pharmacy, Gulbarga, Karnataka.

Stress is a common problem and major health hazard of life. Stress is a particular response of the body by releasing certain hormones like cortisones and adrenaline. This leads to an increase in heart rate, blood pressure, anxiety, depression and hypertension. These anti stress agents resist against aversive stimuli and immunity to give protection against diseases, improve vigour vitality and longevity.

In the present study multi herbal formulation consists of *Withanaia Somnifera, Centella acitica, aspargus racemosus, ocimum santum, embellica officinalis, nigella sativa* and zam zam water were selected for Adaptogenic activity. The formulation was found to be effective at a dose of 180mg/kg.body weight. The formulation was evaluated for Adaptogenic activity swimming endurance test and anoxic tolerance test in mice and cold stress in rat models. Serum levels of glucose, cholesterol, triglycerides and BUN also WBCs and DC were evaluated.

Significant increase in swimming time, anoxic tolerance test was determined by taking the appearance of convulsions as an end point for the increase in stress tolerance time. Cold stress increases the serum levels, which influence the stimulation of hypothalamus to secrete ACTH. Formulation significantly decreases the serum levels of glucose triglycerides, cholesterol and BUN and also increased the count of WBCs.

In the present study it was observed that manifestation of stress effect due to various ingredients present in the formulation it may be concluded that the formulation shows management of anti stress and significantly reduces in enzyme levels.

DP 18 Evaluation of *in-vitro Anti-fungal* activity of *Piper betle* linn. leaf extract

G. Tamilarasi, R. Umamaheswari, AR. Mullaicharam[1] M.Karthikeyan, A.Sheela*, K.Sukumar.

Department of Pharmaceutical Chemistry, Ultra College of Pharmacy, Madurai – 625 020.

1. Department of Pharmaceutics, Nandha College of Pharmacy, Erode.

Piper betle Linn. family piperaceae is an indigenous shrub cultivated in India and Ceylon with oval accuminate green smooth leaves. It is used for internal and external infections, stomach problems aromatic stimulant, laxative contraceptive, digestive, aphrodisiac, carminative, astringent and antiseptic. It is also used in the management of impotence and sexual disabilities and also free radical scavenging activity.

Literature studies reveal the presence of eugenol, piperol A and piperol B and two peculiar isomeric phenols chavicol and chavibetoil and other alkaloids such as Arekene and Arecaine and Arecoline.

Our present study deals with the determination and comparison of antifungal activity of leaf extracts using different solvents. The *in vitro* anti-fungal activity was evaluated using candida albicans and candida Krusei in Muller-Hinton agarmedia. The activity was determined by measuring the zone of inhibition. The results of different extracts were compared and also compared with standard drug Griseofulvin.

Among the various extracts, aqueous and ethanolic extracts exhibit a wide range of anti-fungal activity. Ethanolic extract exhibits significant activity with primary zone of inhibition and the activity was found to be greater than that of the standard drug Griseofulvin.

DP 19 Quality control aspects of flavours

R. Kamaraj[1], Reshma.M*[1], Silpa. B, Madhavi.T Shikha Sinha and Adil Basha

College of Pharmacy, Sri Ramachandra Medical College & Reasearch Institute (DU), Porur, Chennai – 116.

Food flavours are the result of interaction between both volatile and non volatile compounds with human sensors located in the nose and mouth. Flavours consists of both aroma (volatile) and taste (non-volatile). In most foods, volatile compounds contribute more to the overall flavours than non - volatile.

Flavours arises when the appropriate molecules stimulate either the taste or smell senses. The mechanism by which this occurs is influenced by the geometry and functional groups on a molecule.

Components that stimulate the taste senses tend to the non volatile and room temperature and this structures tend to have similar features that are required to interact with the taste receptors on the biouutre. The four basic types of taste compounds stimulate either the sweet, bitter, salty or sours receptors.

Smell (or odour) is often the most important contribution to flavour. For a compound to have an odour, it must be volatile such that it can carry to the nose. It is likely that there is a molecular size limit on compounds possessing smells such that they are volatile at room temperature, almost all known structures with aromas have molecular weights of less than 300 amu.

We are here with emphasizing the quality control aspects of flavours, the parameters like sensory assessments like sweet, bitter, salty, sour, and all over were discussed. Chemists often analysed natural flavours such as vanilla or ginger to determine the component and then aim to synthesize them to make cheaper alternatives to the natural version, where taste is taken into considerations for their quality aspects.

DP 20 Pharmacokinetic studies on rabbits as a tool to evaluate the quality of *Phyllanthus amarus* and *Ricinus communis*.

K. K. Jaripatke, Prateek Patel*, S.N. Menon, R.T. Sane

Therapeutic Drug Monitoring Lab., 194, Scheme No.6, Road No. 15, Sion (East), Mumbai 400 022

Usually a modern drug will consist of the ingredient and excipients. It is relatively easy to trace the pharmacokinetics of the modern drug. In case of herbal medicines, usually most of the over the counter products are polyherbal. There is no component clearly said to be the active principle responsible for the decided medicinal effect. Hence, one needs to establish some phytochemical markers for the identification of the herb(s) in the blood, which can be used to trace the fate of the drug in the living system. This will help us to establish absorption elimination process of the herb. The markers thus obtained need not be the active principle or constituent of the drug. This will help to decide the dosage regime and the therapeutic window of the drug. The present work was undertaken with an objective to establish a phytochemical marker for the detection of *Phyllanthus amarus* and *Ricinus Communis* in the blood of rabbits and to establish the pharmacokinetics of the herb. We were able to identify two components from *Phyllanthus amarus* and *Ricinus Communis* (one for each) in the plasma of the rabbits fed with the whole plant powder of *Phyllanthus amarus* and the leaf powder of *Ricinus Communis* as combined dose. These two phytochemicals were used to establish the pharmacokinetics of *Phyllanthus amarus* and *Ricinus Communis*.

DP 21 Phytochemical and adaptogenic evaluation of *Murraya koenigii* (Kurry patta) in mild chronic unpredictable stress.

K. Sathish*, S. Abel Arulnathan, A. Bhupathy, P. Selva Kumar, Alhas Ja Jiju, M. Ramanathan and B. Suresh

J.S.S College of Pharmacy, Ooty, Tamil Nadu- 643001.

Adaptogenic and antioxidant evaluation of *Murraya koenigii* in mild chronic unpredictable stress model was evaluated in wistar strain rats. Stress in the animals was induced by following the procedure originally used by Pal and Dandya. Twenty one days administration of stress in the animals resulted in weight loss, loss aggressive behaviour and presence of ulcer sores. Administration of fresh leaves of *Murraya koenigii*, during the stress period significantly attenuated the stress induced alterations. The phytochemical

analysis of n-butonol fraction of *Murraya koenigii* revealed the presence of vitamins such as retinol, tocopherol, vitamin C and their R_f values was found to be 0.15, 0.27, 0.49 respectively. The *in vitro* free radical scavenging activity measurement of diphenyl picryl hydrazyl solution have shown good free radical scavenging property in *Murraya koenigii* and the IC_{50} value found to be 220 mcg. The *in vivo* antioxidant property also indicate significant antioxidant property as evidenced by the increase superoxide dismutas (SOD), catalase and reduced lactate dehydrogenase (LDH) and thiobarbituric acid reactive substance levels. The above finding clearly indicate *Murraya koenigii* can be used as an adaptogenic agent and it may be due to presence of aminoacids and minerals.

DP 22 Evaluation of traditional herbal formulation for wound healing activity

Sadat Ali*, Roshan S, Saleem M.A., Abdulla Khan, Omar Khan, Jameel Patel,

Luqman College of Pharmacy, Gulbarga, Karnataka

To evaluate the traditional unani herbal formulation for wound healing activity using albino rats

In the present study multi unani herbal formulation consists of *Withania somnifera, centella acitica, asparagus racemosus, ocimum santum, embellica officinalis,* nigella sativa and zam zam water were selected for wound healing activity. The formulation was found to be effective at a dose of 180mg/kg.body weight. The formulation was evaluated for wound healing activity Incision wounds, Excision wounds and dead space wound models are selected to evaluate the formulation. The acute toxicity was selected based on up and down method.

Significant increase in wound contraction rate, skin breaking strength, epithelisation period was observed. Pro healing action seem to be due to increase in collagen decomposition as well as better alignment and maturation. The incision wound model when observed on the 10th post wounding day. Epithelization was found to be enhanced significantly by formulation as evidenced by the compare with control.

From the results obtained it may be concluded that the Unani Traditional Herbal Formulation is endowed with significant wound healing activity, thereby justifying its use in traditional medicine.

DP 23 Formulation and HPTLC Standardization of " Piles and Constipation Relieving Moolakudaara Thailam (Oil)

S. Manimaran, Sunil Sharma*, K. Chinnaswamy, M.J Nanjan and B. Suresh

Department of Phytopharmacy & Phytomedicine, Ootacamund-1

Moolakudaara thailam is the Siddha formulation consists of myrobalan *(Terminalia chebula)* and castor oil *(Ricimus communis).* This formulation is used to given for piles, bleeding piles and constipation. This thailam was prepared by taking myrobalan kernels, and those kernels were fried in castor oil, when kernels were brown and swollen takenout and finely powdered and passed through the sieve No. 100. This fine powder was then mixed with the calculated amount of castor oil. The prepared thailam (oil) was subjected to HPTLC standardization to estimate the gallic acid content. The thailam was extracted with methanol and methanolic layer was separated and used for HPTLC analysis, using precoated aluminium silica gel 60 F_{254} plates with CAMAG SCANNER III attached with integrated software (Cats 4.06) using standard marker compound, gallic acid. The amount of gallic acid present in the formulation was calculated by comparing the peak area basis. This standardization technique is very much useful for the analysis of various Siddha formulations containing myrobalans.

DP 24 Estimation of Piperine Content in Mayilirakkathi Chooranam, a Siddha formulation by HPTLC technique

S. Manimaran*, K.N Harsha, H.C. Manjunatha, R. Nandeesh M.J. Nanjan and B. Suresh

Department of Phytopharmacy & Phytomedicine, TIFAC CORE HD J.S.S. College of Pharmacy, Ootacamund 643 001, TamilNadu.

Mayilirakkathi chooranam is the Siddha formulation containing the mixture of long pepper *(Piper longam),* cumin *(Cumminum cyminum)* and ash of peacock feathers. Thee above mentioned drugs was cleaned, powdered and passed through 100 mesh. This formulation gives relief from Hiccup and Vomiting in Siddha system of medicine. The prepared chooranam was extracted with methanol and used for High Performance Thin Layer Chromatographic analysis to estimate the piperine content on precoated HPTLC aluminium sheets of Silica gel 60 F_{254} (Merck) and compared with the standard piperine. The mobile phase used was Benzene Ethyl acatate, Diethyl amine (30:60:10). The detection was carried out at 254 nm.

The content of piperine present in the formulation was 0.16466%. This estimation technique is very much useful for the standardization of various Siddha formulations containing Pepper.

DP 25 Herbal cream formulation of *Thespesia papulnea* and its evaluation for wound healing activity

AR. Mullaicharam*, Srithith, R. Umamaheswari, Barish Sunilchowdry, M. Venugopalachakaravarthi**

Nandha College of Pharmacy, Erode - 52. Ultra College of Pharmacy, Madurai

Objective of this study is to find out the wound healing effect of herbal cream in rats. This study was undertaken to develop and evaluate the herbal cream formulation containing the extract of ground wood (Thespesica populnea) and investigate its wound healing activity. In the process of herbal cream formulation, ground wood of *T. Populnea* was selected and preliminary pharmacognostical studies were carried out. Positive results were obtained. The aqueous cream was prepared and evaluated for physical appearance, namely visual appearance, colour, consistency and feel upon application.

The cream was found to be opaque easily spread and produce cooling effect on application and is easily water washable. Physical evaluations such as PH determination, extrudability, syneresis was carried out. Preliminary chemical tests were performed to detect the presence of flavanoids. Wound healing was evaluated using excision model. The reference standard, (0.2/w.w) nitrofurazone ointment, simple cream BP, and Thespesia populnea aqueous extract cream (10% w/w) were applied externally. The observations from wound healing evaluation revealed that the progress of wound healing in the excision wound method for the Thespesica populnea aqueous extract cream was significantly greater than control and reference standard. The results indicate that herbal cream formulation containing aqueous extract of ground wood of Thespesia populnea possess wound healing activity in rats.

Thespesia populnea-Herbal cream – wound healing.

DP 26 Formulation and HPTLC standardization of Piles and Constipation Relieving *Moolakudaara Thailam* (Oil)

S. Manimaran, Sunil Sharma*, Vaibhav Garg, K. Chinnaswamy, M.J. Nanjan and B. Suresh

Department of Phytopharmacy & Phytomedicine, TIFAC CORE in Herbal Drugs, J.S.S. College of Pharmacy, Rocklands, Ootacamund – 643 001,The Nilgiris, Tamilnadu

Moolakudaara thailam is the Siddha formulation consists of myrobalan (*Terminalia chebula*) and castor oil (*Ricinus communis*). This formulation is used to given for piles, bleeding piles and constipation. This thailam was prepared by taking myrobalan kernels, and those kernels were fried in castor oil, when kernels were brown and swollen takenout and finely powdered and passed through the sieve No. 100. This fine powder was then mixed with the calculated amount of castor oil. The prepared thailam (oil) was subjected to HPTLC standardization to estimate the gallic acid content. The thailam was extracted with methanol and methanolic layer was separated and used for HPTLC analysis, using precoated aluminium silica gel 60 F_{254} plates with CAMAG SCANNER III attached with integrated software (Cats 4.06) using standard marker compound, gallic acid. The amount of gallic acid present in the formulation was calculated by comparing the peak area basis. This standardization technique is very much useful for the analysis of various Siddha formulations containing myrobalans.

DP 27 Anti-diabetic study of detoxified extract of *Casearia esculenta* (Roxb)

G. Syamala*, T. Subburaju, Jhuma Deb, E.P. Kumar and B. Suresh

JSS College of Pharmacy, Rocklands, Ootacamund 643 001, Tamilnadu

Modern medical techniques which are in the cure of Diabetes mellitus associated with certain side effects. To alter these, survey of Botanicals provided the information that the detoxified dried bark of *Casearia esculenta* (Roxb) shows the anti diabetic activity. After the collection the drug was authenticated and the detoxification of dried roots had been performed according to the Siddha system of medicine. The detoxified drug were undergone preliminary phyto chemical studies and qualitative analysis studies. Pharmacological screening were carried out using Alloxan induced Wister Albino Rats for single dose study and multidose study at 100mg/kg and 200mg/kg body weight of detoxified plant extract were administered. The blood glucose levels were

measured at particular intervals and the results were analysed statistically. The detoxified plant extract treated animals showed the normal cells of pancreas along with the lowering of the blood sugar level upto 66.15% at 200mg/kg dose level. These results provides the evidence of that the Detoxified plant extracts contain certain Hypoglycemic active principles like poly phenols (4.49%).

DP 28 Studies on ornamental rose petals

R. Vishnudevi , Tatke Pratima

C.U. Shah College of Pharmacy, S N D T Womens University, Juhu Campus, Santacruz (W), Mumbai 400 049

The antibiotics currently available in the market exhibit various side effects and on prolonged usage, the microorganisms develop resistance towards them, hence there is a need for a new class of antimicrobial agents. In search of newer, safer and effective drug molecules it was found that rose petals of various species (normally cultivated) are active against a spectrum of gram positive and negative bacteria. This pioneering work has lead us to conduct a systematic study on ornamental rose petals which are cultivated biotechnologically.

The flowers were collected, petals were separated and dried. The extracts of fresh as well as dried petals were prepared with ethanol. Qualitative analysis of the extracts was carried out to find out the presence of various phytoconstituents. Carbohydrates, flavanoids, tannins, saponins were found to be present. TLC and HPTLC studies were performed on both the extracts. Since tannins were present as major constituent and possess astringent property, they were isolated. TLC and HPTLC studies were performed for the isolated tannins. Antibacterial studies for the extracts and isolated tannins were carried out by agar diffusion method. The standard used in the study was chloramphenicol(100 µg)

The extracts at 100mg and isolated tannins at 50mg showed moderate activity against the tested organisms (gram positive and negative bacteria).

This study confirms the antibacterial activity of the rose petals, thus adding them to the armamentarium of the existing drugs used in the treatment of bacterial infections.

DP 29 Possible side effects, contraindications and drug interactions of Herbal Singles

R. Kamaraj[1], Madhavi.T*[1], Silpa. B, Reshma.M and Shikha

Sinha College of Pharmacy, Sri Ramachandra Medical College & Reasearch Institute (DU), Porur, Chennai - 116

It remains our belief that the herbal supplements sold on this market are safer than the prescription and pharmaceutical counterparts which, in many cases offered for sale with much worse side effect profiles. It is always seek the advice of a health care practitioner before taking any dietary, nutritional, herbal and homeopathic supplement. Here we are tried to give a safety of herbal singles commonly used by people. It is here with emphasized possible side effects contraindication and drug interaction of herbal singles. Eg. Garlic will produce possible side effects like gastrointestinal symptom and pervasiva. It is not advisable drug like Ephedra should not be given condition like glaucoma, pheochromocytoma, progressive systemic diseases, prostate adenoma, restlessness and thyrotoxicosis. *Ginkgo biloba* produce side effects like stomach or intestinal upset, headache, allergic skin reactions. It should not be give condition like abdominal pain, allergy and hypersensitivity. It may interact with anti-thrombolytic drugs like asprin. It is advisable it should not combined with those drugs.

DP 30 Effect of Stem Bark of *Butea monosperma* on acute experimental diarrhoea in Rats

A. Gunakkunru[a], K. Padmanaban[a], P. Thirumal[a], J. Pritila[a], G. Parimala[a], N. Vengatesan[a], N. Gnanasekar[a], J. Britto Perianayagam[b], S.K. Sharma[b]*, K.K. Pillai[c]

a. Department of Pharmacology, K.P. College of Pharmacy, Thiruvannamalai, India.

b. Phytochemistry and Pharmacognosy Division, Faculty of Pharmaceutical Sciences, Guru Jambheshwar University, Hisar, India.

c. Department of Pharmacology, Faculty of Pharmacy, Jamia Hamdard (Hamdard University), Hamdard Nagar, New Delhi-110 062, India.

Diarrhoea is a national problem, especially among children and contributes to much morbidity and mortality. In developing countries, a quarter of infant and childhood mortality is related to diarrhoea. Many plants conveniently available in India are used locally and traditional folklore medicine for diarrhoea and dysentery. The plant *Butea monosperma* (Lam) Kuntz (also known as Bastard Teak; family : Fabaceae) is a medium sized tree native of the mountainous regions of the India and Burma and now grows wild throughout India. The stem bark of this plant is used in indigenous medicine for the treatment of anorexia, dyspepsia, diarrhoea, dysentery, diabetes, ulcers, sore throats and snake bites. Although many chemical constituents kino-tannic acid, gallic acid and proanthocyanidins from the stem bark and gum, (–) medicarpin from stem bark, triterpenoid, pterocarpan, phenol and lipids from stem have been reported from the plant. Based on the traditional use of this plant for diarrhoea, the plant has been selected, and the antidiarrhoeal effect of ethanolic extract of the stem bark of *Butea monosperma* has been evaluated on

several experimental models of diarrhoea in Wistar albino rats. The ethanolic extract of *Butea monosperma* produced significant inhibitory activity against castor oil induced diarrhoea and PGE_2 induced enteropooling in rats. It also reduced gastrointestinal motility after charcoal meal administration in rats. Results obtained establish the efficacy and substantiate the use of this herbal remedy in non-specific diarrhoea, as a folk medicine.

DP 31 Studies on certain medicinal plants and a siddha preparation - 'Pirandai Uppu' in acute and chronic gastric ulcers in albino rats

K. Elango,Eldow Mathew, T. Subburaju[1], Nasa A* and B. Suresh.

Department of Pharmacology and [1]Department of Pharmacognosy, J.S.S.College of Pharmacy, Ootacamund, Tamilnadu-643001.

The antigastric ulcer study for the formulation 'Pirandai uppu' has been compared with the 50% ethanolic extract of the plant *Glycyrrhiza glabra, Coccinia indica* and *Solanum nigrum* with the use of two models for antiulcer study Viz., Cytoprotective models like Ethanol induced acute gastric mucosal lesions in rats and Acetic acid induced chronic gastric ulcer in rats. The results indicated that Pirandai uppu (50 mg/kg), *Glycyrrhiza glabra* (70 mg/kg), *Coccinia indica* (200 mg/kg) and *Solanum nigrum* (75 mg/kg) produced more significant reduction in ulcer index ($p<0.001$) and the same was comparable to that of positive control sucralfate (270mg/kg) under similar condition. It was found that the biochemical estimation Viz., 1) Gastric mucosal defensive factor like estimation of mucosal barrier [and 2)] Antioxidant studies like Catalase, Superoxide-dis-mutase, glutathione, Lipid peroxidase were significantly altered. From the histopathological studies it showed a significant alteration in support of anti-ulcer activity. From all the above results it has been concluded that plants like *Glycyrrhiza glabra, Coccinia indica* and *Sidha* preparation like 'Pirandai uppu' act by altering the defensive factors to produce significant Antiulcer effect.

DP 32 Estimation of piperine content in *Mayilirakkathi chooranam* – A siddha formulation by HPTLC technique

S. Manimaran, Gulshan Setia*, K. Kripesh, Jojo Joseph, Vaibhav Garg, K. Chinnaswamy, and B.Suresh

Dept. of Phytopharmacy and Phytomedicine, J.S.S. College of Pharmacy, Rocklands, PB. NO : 20, Ootacamund – 643 001, (T.N.)

Mayilirakkathi chooranam is the Siddha formulation containing the mixture of long pepper (Piper longam), cumin (Cumminum cyminum) and ash of peacock feathers. The above mentioned drugs was cleaned, powdered and passed through 100 mesh. This formulation gives relief from Hiccup and vomiting. The prepared chooranam was extracted with methanol and used for High Performance Thin Layer Chromatography analysis to estimate piperine content on precoated HPTLC aluminium sheets of silica gel 60 F_{254} (Merck) and compared with the standard piperine. The mobile phase used was Benzene : Ethyl acetate : diethyl amine (30:60:10). The detection was carried out at 254nm. The content of Piperine present in the formulation was 0.16466%. This estimation technique is very much useful for standardisaton of the various siddha formulations containing pepper.

DP 33 Wound healing activity of Leaves of *Dodonaea viscosa.*

K.S.Patil[1], A.G. Jadhav[1], Suresh Babu A.R.[1*], S.C. Chaturvedi[2].

1. KLES's College Of Pharmacy, JNMC campus, Nehru Nagar, Belgaum-10.
2. G.S. I.T.S., Dept. of Pharmacy, Indore.

Dodonaea viscosa commonly known as Sinatha in Hindi, Velari in Tamil, Bandara in Kannada belonging to family Sapendaceae. Occurring almost throughout India in western Himalayas, sarg forests and dry miscellaneous forests. The leaves are somewhat sour and bitter taste used in baths and fomentations.

The present work involves the study of leaves extract of *Dodonaea viscose* for wound healing activity.

The pet ether (40-60°), benzene, solvent ether, ethyl acetate, butanone and butanol fractions of ethanolic extract of *Dodonaea viscosa* leaves were screened for wound healing activity. The dose of 300 mg/kg body weight per oral is subjected on the basis of toxicity studies.

Out of this fractions pet ether (40-60°) fraction, solvent ether and ethyl acetate fraction showed significant wound healing activity.

DP 34 Development of 'Herbosomes' – a value added herbal formulation with standardized botanicals

Kakali Mukherjee*, Kuntal Maiti, A. Wahile, A. Gantait, B. P. Saha, M. Pal and Pulok K. Mukherjee

Natural Product Studies Laboratory, Dept. of Pharm. Technology, Jadavpur University, Kolkata 700 032

Proper investigation and research in phytochemistry and related fields can manifold the enormous blessings of plants. Extensive research in the field of Herbal Drug Delivery System as a means of improving the therapeutic indices of drugs is of prime importance.

Based on the combined approaches of exploration and exploitation in herbal drug delivery, development of 'Herbosomes' can be proved to be a trust-worthy delivery system, having a significant upper hand over the conventional herbal therapy. 'Herbosomes' are advanced form of herbal products in combination with the phospholipids having better absorption and utilization profiles in our body and subsequently produce better therapeutic efficacy than the conventional herbal extracts . This delivery system can markedly alter the biodistribution of their associated drugs, by increasing the drug concentration at the site of infection and inflammation, shifting the distribution in favour of the diseased tissue with increased capillary permeability.

In this study *Andrographis paniculata* has been used as a prototype herb for the treatment of liver complaints in experimental animal model. This is a bitter shrub, well known by the name of Kalmegh. The plant is very useful in general debility, dysentery and certain forms of dyspepsia. The plant is also used in spleen complaints, colic, strangulation of intestine and tropidity of liver. The Hepatoprotective activity is mainly due to the active component andrographolide, a diterpenoid lactone, present in the plant.

This work was undertaken to ascertain the superiority of Andrographis paniculata 'Herbosomes' over the conventional methanolic extract of this plant, using carbon tetrachloride –intoxicated albino rats. The degree of protection of liver was estimated by evaluating the biochemical parameters like serum transaminases (SGPT and SGOT), alkaline phosphatase, total protein and albumin. 'Herbosomes' showed the most significant hepatoprotective activity as compared to conventional methanolic extract of the plant.

The observations may lead to a new line of treatment of liver impairments with therapeutically superior *Andrographis paniculat*a 'Herbosomes' in a better way than the conventional therapy with the standardized extract of the same plant.

We are thankful to Department of Science and Technology, Govt. of India, New Delhi for the necessary financial assistance.

DP 35 Cardiac depressant activity of *Coriandrum sativum*, Linn : A Preliminary study

Patil J.J*., Zambad S.P., Ghaisas M.M. and Deshpande A.D.

Dept. Of Pharmacology, Padmashree Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune – 411 018.

Coriandrum sativum is digestive, carminative, anti-oxidant and diuretic in action. It is also reported for its hypolipidemic and hypotensive effect in rats. In the present study the effect of aqueous extract of *Coriandrum sativum* on frog heart was investigated.

The aqueous extract of *Coriandrum sativum* was prepared by maceration. *In situ* heart preparation was assembled and after basal recording, 0.1ml of Adrenaline was administered to identify the sensitivity of preparation. The effect of various doses of aqueous extract on the amplitude of cardiac contraction and heart rate were recorded. The effect of the aqueous extract on the blood vessels was checked using frog hind limb perfusion.

The result indicated that aqueous extract of *Coriandrum sativum,* dose dependently decreased the heart rate and amplitude of cardiac contraction. The extract has also shown vasodilatory effect, which was evident from the increase in number of drops/min in hind limb perfusion experiment. This indicates that the extract of *Coriandrum sativum* possesses cardiac depressent activity. To assess the probable cause of cardiac depressant action the studies were further extended to estimate the K^+ content of extract and to assess the effect of extract on the frog heart in presence of atropine.

The result of this study indicated that the K^+ ions are absent in the aqueous extract and atropine attenuated the cardiac depressant effect of the aqueous extract of *Coriandrum sativum.* Thus it is evident that *Coriandrum sativum* has cardiac depressant effect, which might be due to the presence of muscarinic principles.

DP 36 Studies on antioxidant activity of *Eucheuma* – an edible seaweed using *In-vitro* methods

Md. Fayaz[2]*, K.N.Chidambara Murthy[1], Salma Khanam[2], G.A.Ravishankar[1]

1. Plant Cell Biotechnology Department, Central Food Technological Research Institute, Mysore 570 013, India
2. Al-ameen college of pharmacy, Bangalore – 560 027, India

Eucheuma is red algae belonging to family Solieriaceae, which contains approximately 45 species and among which only 8-9 are commercially found like *E. alvarizii, E.denticulatum, E. gelatinae, E muricatum* etc. The world production is approximately 28,000 tons per annum. Indonesia and Philippines are major producers of Eucheuma

The present study deals with antioxidant activity of extracts of Eucheuma tested by 1,1- diphenyl-2-picrylhydrazyl method and by measuring hydroxyl

radical scavenging activity. Chloroform: Methanol (2:1) extract at 1000-ppm level of extractives has shown 82.5% scavenging activity. Acetone extract showed 46.04 % scavenging activity at 1000-ppm level of extractives. In case of hydroxyl radical scavenging activity, all the extracts have shown better activity at the concentration of 25 and 50 ppm. Ethyl acetate extract has shown 76.0% activity, Acetone 75.12 %, and Hexane 71.15% activity and Chloroform: Methanol (1:1& 2:1) has shown 52 & 56% activity respectively at the concentration of 50 ppm. The Polyphenol content has shown no direct relation to the antioxidant activity of various extracts. However all the extracts have shown the presence of the polyphenols, apart from this they contain sterols, glycosides and alkaloids which may attribute directly or indirectly to the antioxidant activity. Since Eucheuma is widely cultivated in coastal areas without much of inputs, in term of nutritents and manpower, this can serve as best and economic source of health food or nutraceutical supplement. Hence, it provides an added advantage from the industrial point of view to produce nutraceuticals of economic importance.

DP 37 Development and evaluation of a traditional polyherbal formulation for hepatoprotective activity in albino rats

V.I. Hukkeri[1], R.V. Karadi*[2], R.A. Shastry[3]

1. Dept. of Pharmacognosy and Phytochemistry, KLES's College of Pharmacy, Hubli
2. Dept. of Pharmacognosy and Phytochemistry, KLES's College of Pharmacy, Belgaum
3. S.E.T's College of Pharmacy, Dharwad.

In Ayurveda Navayasa Churna, a polyherbal formulation, is mainly used in the treatment of liver disorders, to cure anemia and heart diseases. In the present study, the traditional polyherbal formulation Navayasa Churna was developed and screened for hepatoprotective activity in albino rats. Acute toxicity study was carried out in albino mice by Up and Down method, the dose was found to be 500 mg/kg body weight. The activity was screened in carbon tetra chloride induced liver damaged albino rats and studied for serum enzyme levels viz.SGPT, SGOT, ALP and histopathology. The result shown significant reduction in elevated serum enzyme levels (due to CCl_4 intoxication) with the formulation treated group which can be comparable with the standard drug, Liv 52.

DP 38 Evaluation of hepatoprotective activity of newly designed herbal formulation

Pravin S. Wakte* Sachin S. Bhusari, Devanand B. Shinde

9, Priyadarhini Colony, N-5/Sector-G, CIDCO, New Aurangabad 431 003

Numbers of medicinal plants have been reported to be useful for the treatment and management of various liver diseases. Such potent Indian medicinal plants are used for the development of multicomponent herbal drug formulation. The objective of this study was to evaluate the hepatoprotective activity of a in-house designed polyherbal formulation containing *Balanites roxburghii, Tinospora cordifolia* and *Piper longum.*

In the present study, the fruit pulp of *Balanites roxburghii*, stem of *Tinospora cordifolia* and dried fruits of *Piper longum* were extracted and using these extracts a formulation was designed which was further investigated for hepatoprotective activity.

All the above mentioned extracts were subjected to hepatoprotective activity against hepatotoxicity induced by CCl_4 (1 ml/kg B.W.) i.p on health adult albino rats of either sex in a group of six animals each. All the animals were divided in four groups, each for normal control, CCl_4 (1 ml/kg B.W.), Liv-52 and the designed formulation respectively. Levels of enzymes like SGOT and SGPT were estimated in serum. Histopathological studies were also done to confirm the biological changes.

Hepatic damage was evidenced by the rise in the levels of SGOT and SGPT in serum and liver showed a tendency to attain near normalcy in animals treated with designed formulation. The values of SGOT (IU/L) and SGPT (IU/L) in serum of CCl_4 administered group (951.8 and 738 respectively) were found to alter towards values (135.6 and 76 respectively) in the formulation administered group. Histopathological study showed well preserved architecture and hepatocytes in normal cord pattern did not show degenerative changes.

The herbal formulation has protected the liver from CCl_4 damage. The study of probable mechanism of action is ongoing and is in progress.

DP 39 Antioxidant studies on the alcoholic leaf extract of *Acalypha indica*

S.Balaji*, Annie Shirwaikar, K. Rajendran, Ram Gopal Bodla

Department of Pharmacognosy, College of Pharmaceutical Sciences, Manipal, Karnataka 576 119

Antioxidants are nutraceuticals, whose deficiency states are associated with numerous

dreaded diseases such as diabetes, cataracts, rheumatoid arthritis, etc. The study was conducted for screening the antioxidant potential of the alcoholic leaf extract of the plant Acalypha indica (Family-Euphorbiaceae). *In vitro* antioxidant studies were carried out using five models viz. DPPH, ABTS, Nitric Oxide, Superoxide dismutase and lipid peroxidation models. Successively increasing concentrations of the extract were estimated for its free radical scavenging activity. The decrease in thiobarbituric acid reactive substances (TBARS) and increase in reduced superoxide dismutase (SOD), nitric oxide, DPPH and ABTS free radicals clearly demonstrated the antioxidant property of ethanolic extract of this plant. The ethanolic extract was found to decrease the free radicals formation in all the five *in vitro* models.

DP 40 Formulation and Evaluation of *Boswellia serrata* Tablets

Arun Shirwaikar[1], Annie Shirwaikar[2], H.N.Aswatha Ram[2], Dinesh Kumar Upadhyay[2], Prithwiraj Mohapatra[2]

1. Department of Pharmaceutics
2. Department of Pharmacognosy, College of Pharmaceutical Sciences, Manipal- 576 119.

An attempt was made to formulate *Boswellia serrata* extract as a conventional tablet using various excipients in different proportions. Herbal raw materials and finished herbal medicinal product specifications were set according to CPMP (Committee for Proprietary Medicinal Products) Eleven such formulations were prepared and evaluated for physical parameters viz., thickness, hardness, friability, weight variation, drug content, disintegration time and drug release pattern. The formulations prepared with different proportions of disodium hydrogen phosphate (DSP) in 10, 15 and 20% as solubilising agent showed maximum drug release. The formulated tablets had better appearance and drug release properties.

DP 41 *In-vitro* antioxidant study of some medicinal plants

Shrishailappa Badami, Vijayaganapathy V*, Prince Francis .M, Nirmal .J, Sandhya Deepa .S, Suresh.B

JSS College of Pharmacy, Rocklands, Ootacamund 643 001 (TN)

A larges number of plants containing phenolics and flavonoids are known to exhinbit potent antioxidant activity. Hence in the present study twelve plant extracts were screened for their antioxidant activity using standard DPPH and Nitric oxide methods. The total phenol and total flavonol contents were also estimated using standard methods.

Among the twelve extracts tested for antioxidant activity using DPPH method, the methanol extract of Cytisus scoparius gave an IC50 value of 36.00 ?2.03 g/ml. The value was found to be more than that of standard ascorbic acid (IC50 18.17 ?1.79 g/ml) and lower than another standard rutin (IC50 43.6 ?1.79 g/ml). The extracts of *Eupatorium glandulosum (leaf), Bacolepis nervosa, Leucas zeylanica, Andrographs paniculata* and *Brugmansia sauveolens* (flower) showed low antioxidant activity. In the Nitric oxide method the IC50 values obtained for *Brugmansia sauveolens* leaf and flower extracts were found to be 596.0 23.58 g/ml and 579.6 9.61 g/ml respectively. The standard rutin showed an IC50 value of 186.5 12.85 ?g/ml in this method. The total phenolic content of *Cytisus scoparius* was found to be the highest. Hence, there is a correlation between the antioxidant activity in DPPH method and the total phenol content in these extracts. However there was no correlation between the activity and the total phenol content in other extracts. The total flavonol content also showed no correlation between its content and the DPPH IC_{50} values.

DP 42 *Dhataki pushpa* as an antioxidant in *Pippalyadyasava*

Jyothi M.Veigas*, Praveen Kumar Reddy, Sujeeth Neerakkal, Misra M.C.

Fermentation Technology and Bioengineering Department, Central Food Technological Research Institute, Mysore – 570 013.

Asavas are herbal based fermentation products, containing self generated alcohol and other components from the ingredients. Herbal based fermented products in Indian system of medicine, are reported to contain antioxidants, which impart disease alleviating properties to these formulations. In order to find out the role of Dhataki flowers, raisins and other ingredients (praksepadravya) in terms of antioxidant property, polyphenols, reducing power activity and free radical quenching capacity of these were determined in ingredients and in fermented asava. It was found that Dhataki flower contributes maximum in terms of polyphenols and thus is an important ingredient. The above-mentioned activities and the extraction of antioxidants from Dhataki flowers under different simulated conditions are reported.

DP 43 Antioxidant activity of a Polyherbal Pain Balm

Kumar.G.S* & S.H.Mishra

Pharmacy Department, Faculty of Technology and engineering, M.S.University of Baroda, Kalabhavan, Vadodara-01

A poly herbal anti-inflammatory balm potent for arthritis and musculoskeletal disorder containing, *Boswellia serrata, Pluchea lanceolata* and Eucalyptus oil as active ingredients, was assessed for its antioxidant activity. Determination of DPPH scavenging activity was used in the present studies being a simple chemical model for evaluation of free radical scavenging activity of any compound.

The Balm showed potent antiradical activity on DPPH model with EC_{50} of 5.48 mcg/ml while, Ascorbic acid and Gallic acid used as standards showed activity at EC_{50} of 3 mcg/ml and at EC_{50} of 1 mcg/ml respectively.

This study therefore suggests the efficacy of Polyherbal pain balm in arthritis and other musculoskeletal disorders with potent anti-oxidant activity.

DP 44 A Study on Vainkutha – *Anisomeles Malabarica*

Sanket Soni, Subrata De

Pharmaceutical Chemistry Laboratory, Gujarat Ayurved University, Jamnagar, Gujarat.

Anisomeles malabarica is an erect shrub belonging to family Lamiaceae. It is commonly known as malbarcatmint distributed throughout South India and in ayurveda commonly known as Vainkutha. The plant is stomachic, caminative diaphoretic, and astrigent. The essential oil obtained from the plant has been reported to be useful in cancer and in rheumatism.

The present study has been undertaken on the powder on the powder of the aerial parts of the plant. It involves the details of powder microscopy, different parameters mentioned in Ayurvedic Pharmacopoeia of India like loss on drying, ash value, acid insoluble ash, extractive values, volatile oil content. The different qualitative tests for the presence of alkloids, steroids, diterpenoids, glycosides, flavanoids, sugar and tannins also been carried out. By using the alcoholic extracts and the volatile oil the TLC Patterns have been evolved. UV spectral study has also been carried out in the laboratory. This data will be useful for the quality control of the *Anisomeles malabarica*.

DP 45 Herbal Alternatives to Synthetic Acid-Base

Shriahailappa Badami, Deepa S *, Nirmal J, Sandhya Deepa E, Vijayaganapathy V, Prince Francis and Suresh B

Department of Pharma Chemistry, JSS College of Pharmacy,Rocklands, Ootacamund 643 001 (TN)

Most of the indicators used in laboratories are organic dyes and are of synthetic origin. Natural pigments in plants are highly colored substances and may show color changes with variation of pH. Hence, in order to identify plant extracts possessing indicator property, the present investigation was carried out. The plant materials selected for the study include *Euphorbia pulcherrima* leaves and flowers of *Streptosolen jamenosii, Bougainvillea* species and *Hibiscus rasasinensis*. The selected plant materials were coarsely powdered and the powder (50g) extracted with methanol (150 ml) in a round bottom flask under reflux for 1 h. The extracts were filtered and the filtrates were used as indicator solutions in various acid-base titration. Three different types of acid-base titration were carried out using the standard indicators mentioned in the Pharmacopoeia. These titrations were also carried out using the specified volumes of mathanolicextracts of the above mentioned plants. The methanol extracts of *Streptosolen jamenosii, Hibiscus rosasinensis* were found to be satisfactory for all the three types oftitrations and vice-versa. The methanol extract of *Euphorbia pulcherrima* was found to be satisfactory only in case of strong acid Vs strong base and weak acid Vs strong base. The methanol extract of *Bougainvillea* species was found to be satisfactory for titration involving strong acid Vs strong base and weak acid Vs strong base and vice-versa. The color changes observed with all the four plants extracts were found to be sharp. In conclusion, the plant indicators can be used successfully and routinely in laboratories.

DP 46 *In-vitro* Antioxidant Properties of Indian Traditional Paan and its Ingredients

Shriahailappa Badami, Jagadish P.C.*, Sujay R. Rai and Suresh B.

JSS College of Pharmacy, Rocklands, Ootacamund 643 001. Tamil Nadu

Indian traditional Paan is being used as a post meal digestive stimulant, astringent, aphrodisiac, nerve tonic, intoxicating and for several other purposes in India and is recommended in ancient scriptures of Ayurveda for normal well being. The betel leaves, betel nut, black catechu, fruits and many aromatic herbs such as cardamom, clove, fennel, gulkhand etc. are used in Paan posses its own medicinal properties, which may be due to their antioxidant properties.

Hence, Paan and its ingredient were extracted with 50% methanol and the extracts were screened for *in-vitro* antioxidant activity by DPPH model and compared with ascorbic acid and rutin as standards. Catechu, rose powder, betel nut and clove extracts exhibits potent antioxidant properties with the IC_{50} values 2.22 ± 0.35, 11.71 ± 0.75, 14.57 ± 1.80 and 16.27 ± 1.95µg/ml, respectively, where as the extracts of Paan, betel leaves and fennel showed moderate antioxidant activity with IC_{50} values 317.10 ± 14.54, 308.09 ± 24.34, and 369.14 ± 17.16 µg/ml respectively. The re-

maining extracts showed low activity. The standards, ascorbic acid and rutin showed IC_{50} values 2.89 ± 0.67 and 9.12 ± 0.69 µg/ml, respectively. These results confirm the common beliefs and traditional uses of Paan in Indian tradition.

DP 47 Phytochemical investigations and antifertility activity of *Woodfordia fruticosa*

Heeshma N. Khushalani*, Pratima Tatke and K.K.Singh.

C.U.Shah College of Pharmacy, S.N.D.T. Women's University, Santacruz (W), Mumbai- 49.

The rise in population in the developing world is overwhelming and this intensifies the need for effective birth control measures. The synthetic agents available today for fertility control produce severe side effects, thus there is a need to explore plant based contraceptive agents. However, a systematic scientific investigation needs to be carried out before these plants can be put to use in modern medicine. The present work reports phytochemical and pharmacological studies of dried flowers of Woodfordia fruticosa Kurz (Fam- Lythraceae).

Flowers of Woodfordia fruticosa were procured, authenticated, powdered and extracted successively (Soxhlet) with various solvents. Individual water and hydroalcoholic (50: 50) extracts were also prepared. The extracts were evaluated for their appearance, pH, extractive value, qualitative evaluation and TLC and HPTLC studies. The qualitative evaluation of all the extracts indicated the presence of carbohydrates, gums, steriods, tannins and flavonoids.

The antifertility activity of three extracts i.e. successive alcoholic, individual water and hydroalcoholic were studied in female albino rats. The extracts were administered orally at the dose level of 100mg/kg body weight. Animals were divided in four groups (one control and three treatment groups). The average numbers of implantation sites and average number of litters delivered were calculated.

The average numbers of implantation sites and the average number of litters delivered in female rats were found to decrease when compared to control.

The alcoholic extract (100mg/kg) showed significant abortifacient activity whereas water and hydroalcoholic extracts (100mg/kg) showed moderate activity as compared to the control.

DP 48 Investigation of wound healing property of *Tridax procumbens*

D.V. Derle, S.A. Katti, G. B. Jadhav *, N.D.M.V.P. Samaj's

Institute of Pharmaceutical sciences, Adgaon, Nasik- 3

Tridax procumbens family. *Compositae* is wild herb growing near the banks of small streams . Fresh juice of leaves is used traditionally for quick healing of topical wounds. It is believed that leaves may contain antiseptic or coagulant or vasoconstrictor property. The effect of fresh juice of leaves was tested on bleeding time and clotting time of normal individuals . It was found that clotting time is not affected but there is reduction in bleeding time. This indicates that juice of fresh leaves of *Tridax procumbens* contains peripheral vasoconstrictor constituent like adrenergic agents.

DP 49 Anti Diabetic activity of a Poly Herbal Formulation *ELAG-8* in Albino Rats

***Hanumanthachar Joshi and Milind Parle**

*S.B.S. P.G. Institute of Biomedical Sciences & Research, Balawala, Dehradun.

Pharmacology Division, Guru Jambheshwar University Hisar, Haryana

Diabetes is characterized by insulin resistance in the liver and peripheral tissues together with a pancreatic β-cell deficit. Modern medicines were able to control this problem but their success is limited. Herbal formulations have become very popular in China and India. In this direction, we have tested a poly herbal formulation *ELAG-8* containing 8 herbs (n=8) of different botanical sources. Individual herbs were kept in diluted water overnight and were crushed to collect the crude extract and all were suspended in water. Gum acacia was used as a suspending agent. Anti-diabetic activity was performed in Streptozotocin (STZ) induced model and glucose tolerance test using albino rats. Glibenclamide (2-5 mg/kg) was the standard. In the STZ model, 65 mg/Kg STZ was administered to the fasting rats by i.p. Blood glucose levels were measured after 48 hr, rats showing 200-300% increase in blood glucose levels was selected for the study. The formulation was given orally for 15 days. Blood samples were collected from the tail vein of rats. The serum glucose concentration was measured using Auto blood analyzer-1000, Bayer, Ireland. On 11th day, mean % reduction in serum glucose levels were 54% (where as 6-8% in control, glibenclamide (2.5 mg/kg)).

In glucose tolerance test, rats were fasted over night. ELAG-8 and Glibenclamide were administrated orally. 2 hr post dose of glibenclamide (4mg/kg) was

administered orally. Blood was collected periodically upto 6 hr and glucose concentration was estimated. *ELAG-8*, reduced the blood glucose concentration (60% compared to normal). Overall, *ELAG-8* exhibited potential anti-diabetic activity. Earlier, individual herbs of the formulation were tested for the activity, few of them were significant, but in combination as PHF, they have exhibited significant anti-diabetic activity in both STZ induced model and GTT model. An approach to being made to formulate an ideal suspension of the same.

DP 50 In-vitro antioxidant activity of *Careya arborea*

Shrishailappa Badami, Manju Mary Cherian*, Choksi Rakshit and Suresh B

JSS College of Pharmacy, Roacklands, Ootacamund 643 001 (TN)

Lipid perioxidation has gained more importance now a day because of its involvement in pathogenesis of many diseases. *Careya arborea* Roxb, (Barringtoniaceae) bark is useful in tumors, cough, bronchitis, catarrah, dyspepsia, colic, haemorrhoids,intestinal worms, dysentery, urorrhea, leucoderma, epileptic fits and eruptive fevers particularly small pox. So far its antioxidant activity has not been carried out. Hence,in the present study, the *Careya arborea* bark extracts were screened for *in-vitro* antioxidant properties using standard procedures. The shade dried bark powder was extracted with petroleum ether, chloroform, ethyl acetate and methanol successively in a sozhlet apparatus and was also extracted separately with methanol, 50% methanol and water and concentrated. These extracts were used for the *in-vitro* antioxidant activity using DPPH, Nitric oxide radical inhibition assay and TBARS methods.

Among the four successive and three crude extracts, the crude extracts showed potent antioxidant activity as evidenced by the results. The IC50 values obtained for the crude methanol. 50% methanol and water extracts in DPPH method were found to be 6.21±0.138, 12.88±0.713, 27.9±1.380 mg/ml respectively. Similarly the IC50 values obtained for the successive methanol extract was found to be 101.66±8.727 mg/ml. The other extracts showed high IC50 values. In the Nitric oxide radical inhibition method the IC50 values obtained for the crude methanol and 50% methanol extracts showed very low IC50 values indicating their potent antioxidant nature. The IC50 values for the crude water extract and successive chloroform, ethyl acetate and methanol extracts were found to be 116.9±3.00, 681.4±10.04, 565±8.21,183±14.85 mg/ml respectively. Petroleum ether extract showed high IC50 value.Similar results were also obtained in the *in-vitro* TBARA assay. All the results confirmed the potent antioxidant activity of *Careya arborea* bark. Preliminary phytochemical studies indicated the presence of flavonoids, saponins, tannins, glycosides and phenolics in the potent crude extracts.Further studies are required to prove the antioxidant activity in animal models and to isolate the active constituents.

DP 51 Antimicrobial activity of various extracts and the Isolated fraction of ethyl acetate extract (Whole Plant) of *"Acanthospermum hispidum* DC" (Asteraceae)

N. Deepa[1]*, T. Latha[2], N.N. Rajendran[1]

1. Department of pharmacognosy, Madras Medical College, Chennai 600 003.
2. Institute of Microbiology, Madras College, Chennai 600 003.

Acanthospermum hispidum DC commonly known as kombumul/mulluchedi. (Family-Asteraceae. N.O. Compositae) is a hispid (presence of rough hairs throught out the plant parts) herb distributed in South America. West Indies and Madagaskar, its native being South America. The plant recently introduced into India and othe rtropical countries, has promising utility in traditional medicine as anthelmentic, abortifacient, treatment of boils, skin diseases ad hypertension. As the plant is being used in skin diseases and in boils, the present study was made to throw light on the Anti-Microbial Activity of the plant extracts [Benzene, Chloroform, Ethyl Acetate, 50% Aqueous Ethanol (1:1)] and isolated fraction of ethyl acetate extract.

Anti-Microbial activity was scored on the basis of standard dilution method (MIC) using Muller Hinton Agar (MH) medium. The zone of inhibition was compared with that of Ciprofloxacin (5μ g/disc) by disc diffusion method.

The results showed significant and potential antimicrobial properties of the extracts and the isolated fractions against the organisms tested. The MIC - minimum inhibitory concentration was found to be 200 μ g/ml except *Staphylococcus aureus* in benzene extract. The zone of inhibition of all the extracts and the isolated fraction was comparable with that of Ciprofloxacin with some organisms and a few gave a bigger zone of inhibition.

Hence the present study may probe a way for the development of potent phytomedicine against various organisms.

EP$_1$ Studies on neuromuscular blocking activity of synthetic compound

S.L. Bodhankar, K.R.Biyani*

S.N. Institute of Pharmacy, Pusad 445 204

The important unwanted effects of available neuromuscular blocking agents are prolonged apnoea and cardiovascular collapse resulting from histamine release.

In a view of above-mentioned unwanted effects of neuromuscular blocking agents, along with the problems of isolation and purification of curare, search for new drug devoid of cardiovascular effects and histamine release is going on. Dr.D.P.Jindal from Pharmaceutical Chemistry Department of Institute of Pharmaceutical sciences, Punjab University, Chandigarh has synthesized new DPJ series of compounds.

The aim and objective of current investigation was to determine the neuromuscular blocking activity of DPJ-726 using isolated frog rectus abdominus muscle preparation. Acetyl Choline (Ach) produces a dose dependent contraction of rectus abdominus muscle of frog through stimulation of nicotinic receptors. It is an extremely useful preparation for showing the actions of such compounds which block transmission at neuromuscular junction acting in the same way as an excess of 'Ach' i.e. persistently depolarizing blockers. We have used Ach induced contractions of isolated rectus abdominus muscle of frog to understand the type of antagonism i.e. competitive or non-competitive. Dose response curve of Ach (1 mg/ml) was obtained. Then DPJ-726 (1 mg/ml) was added to the ringer solution and tissue was irrigated with DPJ-726 containing ringer solution for 30 minute. The concentration response curve (CRC) of Ach was repeated in the presences of DPJ-726.

The results obtained in present investigation indicated the competitive antagonism of Acetyl Choline (1 mg/ml) by DPJ-726. Concentration Response Curve of Ach in the absences and presences of DPJ-726 was plotted and compared. Parallel shift of CRC to right was found in the presences of DPJ-726. However present investigation indicate competitive antagonism of Ach by DPJ-726.

EP$_2$ 4-Amino butyrate aminotransferase (GABA-T) inhibition as a possible mechanism of some novel anticonvulsant aryl semicarbazones

J. Vaigunda Ragavendran*, R. Thirumurugan, I. Sridharan, D. Sriram and P. Yogeeswari

Pharmacy Group, Birla Instititute of Technology and Science, Pilani-333 031.

Some 2,3-disubstituted phenyl semicarbazones are novel anticonvulsant compounds with wide spectrum of activity against Maximal Electroshock (MES), subcutaneous pentylenetetrazole (sePTZ) and subcutaneous Strychnine (scSTY)-induced seizures. The mechanism of its anticonvulsant action remains to be determined. We have investigated the effects of some representative aryl semicarbazones on 4-amino butyric acid (GABA) levels, in different rat brain regions. These compounds were found to elevate GABA levels in rat brain and hence were further examined for the effect on GABA-T, an enzyme that metabolizes GABA. *In vitro* enzyme inhibition studies were carried out for a period of 12h using spectrophotometric determination. Some compounds inhibited the enzyme and their qualification of inhibition (IC_{50}) is in the process of determination. The results indicated that the anticonvulsant action of aryl semicarbazones was mediated via., the GABA ergic system.

EP$_3$ Pharmacological evaluation of aryl (heteroaryl) semi (thio) carbazones for CNS activity

R. Kavya*, R. Thirumurugan, D. Sriram and P. Yogeeswari

Pharmacy Group, BITS, Pilani-333 031.

Several aryl semicarbazones have exhibited potent anticonvulsant activity. In the present study, various novel aryl (heteroaryl) semi (thio) carbazones were subjected to a battery of CNZ pharmacological studies in animals that included (1) epilepsy models like maximal electroshock (MES), subcutaneous pentylenetetrazole (scPTZ), subcutaneous picrotoxin (scPIC), seizure models, (2) behavioural impairment study using actophotometer, (3) motor impairment study using rotorod and (4) CNS depressant study using Porsolt's swimpool test. Most of the aryl semicarbozones were found to show protection in all the seizure models with lesser effect on behavioural and motor impairment test. The benzothiazolyl-2-thiosemicarbazones showed CNS depressant activity and anticonvulsant activity in MES test.

EP$_4$ Anxiolytic effect of Zingiber officinale on animal models of anxiety

Sherikar O. Ushir Y and Iyer M.

Dept. of Pharmacology, M.G.V's College of Pharmacy, Panchavati, Nashik – 422 101

To study the anxiolytic effect of Zingiber officinale on animal Models of anxiety based on exploratory behavior.

Petroleum ether extract (PE) and methanol extract (ME) Was assessed for their anxiolytic activity. The PE (25,50 & 100 mg/kg), ME (25,50 & 100 mg/kg) were administered intra-peritoneally.

The anxiolytic activity was studied using elevated plus maze (EPM) Paradigm, Light:Dark apparatus(LDA) and Open field apparatus (OFA).

Dexamethasone (2mg/kg) was used to induce anxiety And diazepam (1mg/kg) as a standard anxiolytic drug.

In EPM, PE increased the time spent in open arms whereas ME. Increased the number of entries in open arms and the number of head dips. In Light:Dark apparatus, PE increased the time spent in lit zone. ME Increased the number of rearing and the transits. In OFA, ME increased the number of squares traversed.

Thus, rhizome of Zingiber officinale contain bio-active Principle(s) which may possess anxiolytic activity. Anxiolytic, Zingiber officinale, diazepam.

EP$_5$ Modulatory effect of PDE 5 inhibitors in diabetic neuropathy

Chandrashekhar S. Patil*, Vijay Pal Singh, Naveen Jain[a] and Shrinivas K. Kulkarni

Pharmacology Division, University Institute of Pharmaceutical Sciences,

Punjab University, Chandigarh, 160 014

a. Research and Development Division, Panacea Biotec Ltd., P.O. Lalru, Punjab- 140501

Diabetic neuropathy is one of the most frequent peripheral neuropathies associated with hyperalgesia and hyperesthesia. Besides alteration in the levels of neurotransmitter, alteration in the neuronal nitric oxide synthase (nNOS) is a key in the pathogenesis of diabetic neuropathy. The present study was aimed to evaluate the role of PDE5 inhibitors on nociception in streptozotocin-induced diabetes in animal models of peripheral nociception (writhing assay in mice and paw hyperalgesia test in rats). Diabetic animals showed a significant decrease in pain threshold as compared to non-diabetic animals in both the test, indicating diabetes induced hyperalgesia in mice and rats. PDE5 inhibitors (sildenafil and zaprinast) significantly increased the pain threshold in both diabetic and non-diabetic animals. However, L-NAME, a non-specific NOS inhibitor and methylene blue, a guanylate cyclase inhibitor blocked the antinociceptive effect. The per se administration of L-NAME or MB augmented the hyperalgesic response in diabetic animals with little or no effect in non-diabetic, which indicates the alteration of NO-cGMP pathway in diabetes. The results in the present study demonstrate the decreased cGMP content in diabetic animals, which may be due to down regulation of nNOS activity, suggesting the decreased nNOS-cGMP system may play a crucial role in the pathogenesis of diabetic neuropathy.

EP$_6$ Aggravation of inflammatory bowel disease by cyclo-oxygenase inhibitors in rats

Vijay Pal Singh*, Chandrashekar. S. Patil, Naveen. K. Jain[a] and Shrinivas.K.Kulkarni

Pharmacology Division, University Institute of Pharmaceutical Sciences,

Punjab University, Chandigarh, 160 014

a. Research and Development Division, Panacea Biotec Ltd., P.O. Lalru, Punjab- 140501

The stimulation of intestinal epithelial cyclooxygenase enzyme and their inhibition has the potential to increase the understanding of this pathway in the intestinal inflammation. The aim of the present study was to determine the contribution of cyclooxygenase enzyme and effect of its modulation on specific prostonoids in *in-vivo* Dextran Sodium sulphate (DSS) stimulated distal colon tissues. Longitudinal colon tissue sections from DSS treated rats exhibited noticeable inflammation, altered contraction, myeloperoxidase activity, oxidative stress The flare of the colon was further worsened in terms of all the parameters and reduction in PGE_2 levels by co-administration of non-selective and selective cyclooxygenase inhibitors with DSS. The present study suggested the role of prostaglandins (specific to PGE_2) in colonic mucosal defense similar to that reported earlier for upper gastrointestinal tract.

EP$_7$ Studies on insulin sensitizing action of Pioglitazone in Streptozotocin treated high fat diet fed rat

Bhoomi V*, Srinivasan K, Kaul CL and Ramarao P.

Cardiovascular and Receptorology Laboratory, Department of Pharmacology and Toxicology, National Institute of Pharmaceutical Education and Research (NIPER), Sector-67, S.A.S. Nagar, Punjab-160062, India.

The objective of the present work was to study the effect of insulin sensitizing action of pioglitazone on plasma glucose, insulin and lipid parameters in streptozotocin (STZ) treated high fat diet (HFD) fed rat (HFD-STZ), which closely replicate metabolic characteristics of human type 2 diabetes. Male Sprague-Dawley rates (160-180g) fed with HFD for two weeks resulted in mild hyperglycemia and marked hyperinsulinemia, hypertriglyceridemia, hyper-cholesterolemia along with certain other insulin resistance characteristics in comparison to normal pellet diet (NPD) fed rats. Insulin level of HFD rats decreased to a level comparable to control NPD fed rats upon

injection with STZ (35 mg/Kg i.p.). In addition, marked elevation in plasma glucose, triglyceride and cholesterol levels observed after STZ injection. Pioglitazone (10 mg/kg), an insulin sensitizer administered orally once daily for 7 days significantly reduced the plasma glucose and triglyceride without altering plasma insulin level. However, acute dose of sulfonylurea compound, glipizide (5 mg/kg, p.o) caused significant reduction in plasma glucose and triglyceride levels associated with significant increase in circulating plasma insulin concentration. In conclusion, pioglitazone exhibited potent insulin sensitizing activity in STZ treated HFD fed rat model and this model can be used for the screening insulin sensitizer.

EP$_8$ Mechanistic appraisal of antidiabetic activity of a Thiazolidin-4-one derivative in male Wistar rats

Vinu ,C.A , Khanna,V* and Kutty, G.N

Department of Pharmacology, College of Pharmaceutical Sciences, Manipal-576119

The compound under investigation, NAT, is a thiazolidin-4-one derivative having a nicotinyl moiety in its structure. Earlier work had revealed its hypolipidemic and hypoglycemic activities. Present study aims to find out if NAT possessed a dose dependent hypoglycemic effect and its possible mechanism of action. NAT, 2(4-methoxyphenyl)-3-nicotinamidothiazolidin-4-one was synthesized from nicotinic acid through a series of standard steps involving the ester, acid hydrazide, Schiff base and the thiazolidin-4-one. The structure was confirmed through spectral analyses (IR,NMR). The compound was tested for hypoglycemic activity in normal rats and in rats with streptozocin-induced diabetes. In the latter group of animals, three doses of NAT were used.. Glibenclamide was used as standard drug and nicotinic acid was used for comparison. The parameters determined were: blood glucose on day 1, day 5 and day 10; plasma insulin on day 10; hepatic glycogen and pancreatic TBARS on day 10. Results were analyzed by one way ANOVA (with post hoc) and paired 't' test. NAT produced significant reduction ($p<0.01$) in blood glucose at all dose levels compared to control. It also produced significant reversal ($p<0.001$) of depleted liver glycogen compared to diabetic control. No effect on plasma insulin was observed. NAT at intermediate dose showed significant reduction ($p<0.05$) in TBARS level compared to diabetic control. Although no conclusive statement could be made regarding the exact mechanism of action of NAT, based on the findings of the present study we could say that its mode of action is different as compared to glibenclamide.

EP$_9$ Role of dopamine on working memory process with haloperidol in rats

Manogaran E*[1], Ramanathan M[2], Asrafali M[1], Nazzer H[2], Rajesh R[2], Rajagopal K[1] and Suresh B[2].

1 Sanjivani College of Pharmaceutical Sciences Khetri, Rajasthan-333503.

2 JSS College of Pharmacy Ooty, Tamil Nadu-643001.

Behavioural Pharmacology and neurobiological studies have provided evidence for a dropaminergic involvement in learning and memory. The participation of dopamine in cognitive function suggested that the important role of dopamine (DA) play in attention and reward mechanisms in the brain. Experimental evidence indicates that depletion of DA in the frontal cortex induced by the injection of 6-OHDA impair the memory performance in non-human primates. The working memory study was evaluated in adult inbred Wister strain albino rats of either Sex. Haloperidol (0.1 mg/kg : i.p.) did not alter the maze performance as observed by no change in the total trails, total time and total number of days to learn the given task in comparision to the control group. However, they committed more error during learning process, which indicate the working memory deficit with haloperidol (HPL). After 2 weeks interval in relearning process, HPL treated groups committed less errors and taken less time to learn the task in comparision to the control group.

Elevation of free radicals and decreased protein levels were indicated in the degenerative conditions like parkinsonism and Alzheimer's disease. HPL slightly elevate the brain cortex antioxidant levels such as catalase, and glutathione peroxidase. There was slight increased protein level in the brain cortex and ponsmedulla regions with HPL treatment was noticed. From these observations, it can be concluded that haloperidol treatment may influence to altered the working memory performance during learning period. HPL may exhibit better activity in the relearning process than acquisition and working.

EP$_{10}$ Evaluation of Antiurolithiatic activity of *Aerva lanata* in surgical insertion of foreign body (Zinc Disc) induced urolithiasis

Suresha.B.S.,* H.C.Satheesh and Rema Razdan

Visveswarapura Institute of Pharmaceutical Sciences, 24 Main Road, 25 Cross Road, KIMS Building, BSK 2 Stage, Bangalore 560 070

The multicausal nature of urolithiasis has made it difficult to understand the process of stone formation clearly in patients . Hence, experimental urolithiasis in

animals has been studied extensively by using foreign body insertion technique. Ethylene glycol has been used as a standard tool to enhance the stone formation in the urinary bladder.

Aerva lanata juss (Family: Amaranthaceae) also known as Pashanabedha is used traditionally in ayurvedha in the states of Tamilnadu, Andrapradesh and Karnataka. The present study was conducted to assess the efficacy of the ethanolic extract of the whole plant of *Aerva lanata* (300 mg/kg/day,p.o.) in preventing the formation and / or dissolution of preformed calculi on zinc disc implants in the urinary bladder of rats. The influence of the extract on urinary electrolytes which play an important role in urolithiasis was also evaluated.

The zinc disc implanted rats were divided into 5 groups of 6 animals each.

Group I: (Control) - 1% Ethylene glycol mixed with drinking water for 4 weeks.

Group II: (Prophylactic) Ethanolic extract of *Aerva lanata* (300 mg/kg/day,p.o.) along with ethylene glycol mixed with drinking water for 4 weeks.

Group III: (Curative) Ethylene glycol mixed with drinking water for 4 weeks. Subsequently ethanolic extract of *Aerva lanata* (300 mg/kg/day,p.o.) administered orally for 4 more weeks.

Group IV: (Spontaneous dissolution) Ethylene glycol mixed with drinking water for 4 weeks. Later drinking water for 4 more weeks.

Qualitative analysis of stone deposits showed the calculi to be of magnesium ammonium phosphate type. Treatment with ethanolic extract of *Aerva lanata* (300 mg/kg/day,p.o.) for 4 more weeks did not significantly reduce the weight of stone deposits on the implanted zinc discs in prophylactic group and in the curative group.

The extract (300 mg/kg/day.p.o) did not significantly decrease the urinary excretion of phosphorous, calcium and oxalate in prophylactic group.

The extract (300mg/kg/day,p.o) did not significantly change the urinary excretion of phosphorus, magnesium and oxalate in curative group.Thus the ethanolic extract of *Aerva lanata* Juss at a dose of 300mg/kg/day,p.o did not affect the formation of calculi nor the dissolution of performed stones in the zinc disc implanted urolithiasis.

EP 11 Effect of Losartan pretreatment and co-treatment on Haloperidol induced catalepsy in mice

P.V.Pandi*, P.A.Thakurdesai and A.N. Nagappa

Pharmacy Group, BITS, Pilani-333 031

Angiotensin II (Ang II) is known to stimulate catecholamine release, including dopamine. Ang II receptor mediating this effect in the brain is thought to be the AT1 subtype. It is postulated that this Ang II receptor is located on presynaptic nerve terminals. It has recently been shown that the mouse brain contains an abundance of AT1 receptors in regions enriched with dopaminergic nerve terminals, including the nucleus accumbens. There is a functional evidence that losartan, crosses the blood brain barrier. Therefore it was planned to investigate the effect of Losartan potassium on catalepsy- a dopamine-mediated behavior in albino mice. Effect of losartan potassium (100 mg/kg, ip) pretreatment and co-treatment on Haloperidol (0.1 mg/kg, ip) induced catalepsy was studied and compared with catalepsy scores of Haloperidol per se, and losartan per se treatment at the time points 0.5, 1.0, 2.0, 3.0, 4.0, 5.0 and 6.0 hr after Haloperidol treatment. Animals were tested for the presence of catalepsy by placing both front paws on a 4 cm high wooden block, and time for which animal maintained the imposed posture was scored. The statistical significance of difference between means was calculated by the student's unpaired t test.

Losartan potassium alone was found to induce catalepsy at 3hr and also potentiated Haloperidol induced catalepsy both pre-treated (2 hr prior) and co-treated with Losartan potassium, at 0.5 hr and at 3 hr. respectively. Our results indicate that central Renin Angiotensin System (RAS) by exerting a modulatory influence on the striatal dopaminergic system may influence the functioning of the extra pyramidal motor system.

EP 12 Study of antidiarrhoeal and anti motility activities of aqueous extract of leaves of *Cocculus hirsutus* DC in laboratory animals

B.B.Jain*, A.D.Danve, A.C.Shah, , S. L. Bodhankar

1. Department of Pharmacology, Poona College of Pharmacy, Bharati Vidyapeeth Deemed University, Erandwane, Pune 411 038

Juice of leaves of *Cocculus hirsutus* DC has been reported to be effective in treatment of eczema. There is paucity of data on its gastrointestinal activity. The objective of present study was to evaluate antidiarrhoeal and antimotility activities of aqueous extract of leaves of *Cocculus hirsutus* DC in laboratory animals.

For anti diarrhoeal activity 'Castor oil induced diarrhoea method' was used. Wistar rats of either sex were divided in five group (n=6). Group I was control. Group II received Loperamide 3mg/kg p. o. Group III, IV and V received 50, 100 and 200 mg/kg p.o. aqueous extract. The result showed increase in

defecation time at 200mg/kg p.o. of extract, indicating antidiarrhoeal activity. The extract was less potent than Loperamide. 'Charcoal meal test' was used for studying antimotility activity. Swiss albino mice were divided into six groups (n=6). Group I was control. Group II received Atropine Sulphate 5mg/kg. Group III received Loperamide 3mg /kg p.o.. Group IV, V and VI received 50, 100 and 200 mg/kg p.o. aqueous extract respectively. At 200mg/kg dose of aqueous extract distance travelled by charcoal had significantly reduced confirming antimotility activity. Atropine Sulphate and Loperamide were more potent than the aqueous extract.

It is concluded that aqueous extract of leaves of *Cocculus hirsutus* DC has significant antidiarrhoeal and antimotility activities.

EP 13 Exploration of antidiabetic potential of *Berberis aristata* Dc in wistar rats

Narayanwal, N.R., Robby, Z.T.*, Rao, C.M.

Dept of Pharmacology, College of Pharmaceutical Sciences, Manipal - 576119.

Diabetes mellitus, a clinical syndrome typified by chronic hyperglycemia and disturbances in carbohydrate, fat and protein metabolism, is associated with absolute or relative deficiency of insulin.

The present study on an Indian plant *"Berberis aristata* DC " has been aimed for its possible antidiabetic potentials using both aqueous and ethanol extracts. Qualitative tests established the presence of alkaloids, saponins, tannins, phenolic compounds, flavonoids, carbohydrates, proteins and free amino acids.

The extracts were studied on streptozotocin induced IDDM and streptozotocin + nicotinamide induced NIDDM models of diabetes in albino rats of either sex weighing 200- 250 g and with an oral dose of 500 mg/kg. Following treatment for 16-20 days, the following parameters were monitored. Parameters like FBS (mg/dl), liver glycogen (mg/g), TBARs in pancreas, proteins in pancreas. Results were analysed using ANOVA followed by Scheffe's test.The extracts showed hypoglycemic activity in both NIDDM and IDDM models and the effects were comparable with that of the standard drug glibenclamide. Drug treatment significantly reversed the diabetes induced depletion of liver glycogen. The pancreatic TBARs results showed that none of the treatments including the standard drug did significantly alter the oxidative stress caused by streptozotocin.

It is evident from results that the extracts of "Berberis aristata DC" have got hypoglycemic activity in normal as well as in diabetic rats. Efficacy parallels that of the standard drug.

EP 14 Evaluation of analgesic, anti-inflammatory, anti-pyretic and anti-oxidant property of ether extract of *Gardenia gummifera* Linn

Sathish Kumar Mothkuri*, Kishore.G.S, Pavan.B, P.Vasanth Raj, Dhanaraj .S.A, and B.Suresh

Department of Pharmaceutical Biotechnology, J.S.S.College of Pharmacy, Rocklands, Ooty.

The Dikamali gum is a resinous exudation obtained from leaf buds, young shoots of *Gardenia gummifera* linn. The *Gardenia gummifera* was extracted by using diethyl ether as solvent. The chemical tests were done and the presence of flavanoids in the extract were identified.

The analgesic activity was screened by acetic acid induced writhing method. Wistar albino mice (25-30gms) were used for study. Paracetamol (100mg/kg) used as standard. Extract was administered at 3 dose levels (100,200,300 mg/kg). The average no of writhing in 20minutes showed Paracetamol 22.8±1.27, extract 100 mg/kg 25.6±1.24, extract 200mg/kg 19.4±0.89 and extract 300mg/kg 14.4±0.93.

The anti-inflammatory activity was determined using formalin induced paw edema method, in Wistar albino rats (150-200gms) by using Plesthymograph. Diclofenac sodium (25mg/kg) was used as standard drug. The 3 doses (100,200,300 mg/kg) of extracts significantly reduce the paw edema from 30mtrs onwards.

The anti-pyretic activity was determined using pyrexia induced rat (150-250gms) of either sex. Paracetamol was used as the standard. The mean body weight temperature was shows standard 34.35±0.08 and extract 100mg/kg 34.18±0.154.

The antioxidant property of *Gardenia gummifera* extract was carried out by TLC-method using folin cisciliate reagent. The antioxidant activity was similar to -Tocopherol (standard anti-oxidant) from this method it is evident that flavanoids obtained from ether extract protected the bleaching of beta-carotene in sunlight. Also confirms the presence of the free phenolic groups.

EP 15 Study of anti-inflammatory activity of some ethnobotanicals in Albino rats

Indurwade.N.H., Biyani K.R., Jaju S.B., Phutane G.P.*

S.N. Institute of Pharmacy, Pusad. Distt. Yavatmal (M.S.)

Herbal remedies are getting increasing patient acceptance, as they are devoid of typical side effects of allopathic medicines.

Inflammation is a disorder which when treated with NSAIDs causes various side effects like gastritis, ulcer index, and allergy etc. this has created an urge to discover the potential herbs to treat inflammatory disorders.

Some ethnobotanical plants found in Vidarbha region viz. *Putranjva roxaburghii* (aqueous extract), and *Cleistanthus collinus* Benth (alcoholic extract) belonging to family *Euphorbiaceae* were evaluated for anti-inflammatory effect by Carrageenan induced rat paw edema method in albino rats.

The percent edema inhibition after an oral administration of 100mg/kg was found to be 69.24% and 56.25% respectively.

The plants have been used since long time by the tribal people in Vidarbha region and can provide a better alternative to NSAIDs. Development of formulation of herbal extract may provide a platform for future investigation and better and cheap option to NSAIDs.

EP 16 Evaluation of hepatoprotective activity of whole plant extracts of *Scoparia dulcis* L.

Dr. Rema Razdan, Praveen T.K.*

Visveswarapura Institute of Pharmaceutical Sciences, 24 Main Road, 25 Cross Road, KIMS Building, BSK 2 Stage, Bangaore 560 070

Scoparia dulcis L.(family: Scrophulariaceae) is an herb native of tropical America and naturalized in tropics and widely present Karnataka. This plant has been traditionally used to cure many liver aliments. A study was conducted in albino rats to evaluate the antihepatotoxic activity of aqueous and alcoholic extracts of *Scoparia dulcis* L. in carbon tetrachloride induced cirrhosis.

Cirrhosis was induced by simultaneous administration of carbon tetrachloride inhalation for 10 minutes, twice a week and phenobarbitone (0.5 g/l) in drinking water for a period of 8 weeks. Simultaneous treatment with aqueous extract (0.5 g/kg, p.o. daily) and alcoholic extract (0.5 g/kg, p.o. daily) significantly protected the carbon tetrachloride induced hepatotoxicity.

The degree of hepatoprotection was measured by using biochemical parameters like ASAT, ALAT, ALP and total proteins in serum and by studying the liver histopathology. The results obtained from the above study indicated that the aqueous extract showed most significant activity, alcoholic extract also exhibited potent activity but less than aqueous extract. The above results were comparable to standard hepatoprotective silymarin.

EP 17 Study on anti-inflammatory activity of *Fleuggea virosa* (Euphorbiaceae) by oral and topical route of administration

Indurwade N. H.* , Biyani K. R., Jaju S. B., BelgamwarV. S. , Phutane G. P.

S. N. Institute of Pharmacy , Pusad, Distt. Yavatmal (M.S.)

Most of the NSAIDs available in the market possesses good anti-inflammatory activity but are associated with severe adverse effects like gastritis, ulcer index and GI Toxicity.

Traditional knowledge of herbs is valid and necessary and awaits its currently relevant wider application for human benefit. However, attempt was made to evaluate traditionally used *Fleuggea virosa* Baill (Euphorbiaceace) for its anti-inflammatory activity.

In the present study, alcoholic extract of *Fleuggea virosa* (100mg/kg P.O.) was evaluated for anti-inflammatory activity by Carrageenan induced rat paw edema method. The studies showed significant inhibition of inflammation (78.58%) induced by Carrageenan (1% w/v) in albino rats. The results obtained were boost for further investigation of extract by topical route of administration. The gel containing 0.1 %w/w alcoholic extract of *Fleuggea virosa* was prepared by using Polyvinyl alcohol as gel base and evaluated for anti-inflammatory activity. Significant percent inhibition of edema (76.93%) was found at 3 hrs. after single application (0.5g) of prepared gel. If further studies confirm the stability of novel herbal gel, it can stand as a better option for marketed NSAID preparations.

EP 18 Formulation, development and evaluation of novel herbal anti-inflammatory gel

Biyani K. R.*, Indurwade N. H., Jaju S. B., Belgamwar V. S., Phutane G. P.

S. N. Institute of Pharmacy , Pusad, Distt. Yavatmal (M.S.)

Recommended chronic use of NSAIDs in arthritis & other inflammatory disorders are associated with severe adverse effect like gastritis, ulceration, GI toxicity & allergic reactions. Traditionally used topical application of herbal 'Lep' & 'Poultice' boost idea regarding scientific & systemic study of such herb.

However, attempt was made to formulate and evaluate anti-inflammatory gel containing 0.1% w/w alcoholic extract of *Flueggea virosa* Baill (Euphorbiaceae) by Carrageenan induced rat paw edema method.

In the present study different gel formulation of 0.1% w/w *Flueggea virosa* alcoholic extract were prepared using Carbopol-940, Hydroxy Propyl Mehtyl Cellulose, Blend of Hydroxy Propyl Mehtyl Cellulose with Carboxy Methyl Cellulose & Polyvinyl Alcohol, as gel bases respectively. All the formulations were evaluated for anti-inflammatory activity by Carrageenan induced rat paw edema method in Albino rats.

Gel formulated using Polyvinyl alcohol and blend of Hydroxy Propyl Mehtyl Cellulose with Carboxy Methyl Cellulose as gel bases showed significant percent edema inhibition (76.93% & 46.16% respectively) after single application of 0.5 gm.

If further studies confirm the stability of Polyvinyl Alcohol gel containing 0.1% alcoholic extract of *Flueggea virosa*, it can stand as a cheap and better option for our society.

EP 19 Effect of *Calotropis procera* root extract on physical and biochemical profiles of healing

Jagadish V. Kamath[a]* and A.C. Rana[b]

a. Department of Pharmacology, Krupanidhi College of Pharmacy, Sarjapur Road, Koramangala, Bangalore 560034, India

b. Department of Pharmaceutical Sciences, Dr. H.S. Gour University, Sagar 470003, M.P., India

Calotropis procera (Ait) R Br is a wild shrub, which grows up to a height of 1- 2 m and belongs to family Asclepiadaceae. The medicinal potential of *Calotropis procera* has been known to the traditional systems of medicine. The plant is known as Madaar in Unani medical system and Arka in Ayurvedic medical system. The alcoholic extract from different parts has been found to possess antimicrobial activity. Prevention of microbial contamination of wound facilitates repair. In view of this, the present study was aimed at investigating the unexplored effects of ethanolic extract of *Calotropis procera* roots (CPA) on wound healing. The effects of CPA were studied in albino rats on three wound models viz. excision, incision and dead space wounds. The extract was administered orally for all wound models and its effect was compared with control. The extract showed promising prohealing action at the dose level of 125 mg/kg and 250mg/kg (1/4 of LD_{50}) body weight, as evidenced by increased tensile strength (wound breaking strength), hydroxyproline content (measure of collagen) and decreased period of epithelization.

EP 20 Antiseptic and wound healing activity of *Sida spinosa*

M.N.Satish Kumar., Ankur Patel*, Janmeya Jana, T.Subburaj, K.Elango, K. Chinnaswamy and B.Suresh

J.S.S College of Pharmacy, Rocklands, Ootacamund-643 001- Tamilnadu

Herbal medicines are of great importance to the health of individuals, in India the traditional information claims that herbs have been used for treating various infections and diseases. But scientific validation of the same has given less attention. *Sida spinosa* claimed as antiseptic and for treatment of wounds by folk fore practice. The present work was carried to evaluate antiseptic and wound healing properties for *Sida spinosa*. The reports of *in vitro* antifungal and anti bacterial studies showed, prominent inhibitory action against all strains. External application of extracts (prepared as gel) for 14 days in both infected and non-infected wound produced effective healing. The reports of present findings suggests that antiseptic and wound healing activity of *Sida spinosa* could be due to increased epithelial migration and also promotion of contractions of myofibroblasts.

EP 21 Hepatoprotective effect of fruits of *Capparis moonii Hook. f.* Thoms

R. Ramachandram, Mohd. Ali, M. R. M. Rafiullah *, Showkat R. Mir & Reni Kapoor

Department of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Jamia Hamdard, New Delhi-110062

Capparis moonii Hook. f. Thoms. (Family Capparidaceae), commonly known as Rudanti,, is an indigenous Indian drug. It has been known for its anti tubercular activity. b-Sitosterol, rutin and L-stachydrine have been so far isolated from the fruit. The ethanolic extract of fruits of *C. moonii* was screened for hepatoprotective activity in Wistar albino rats with carbon tetrachloride-induced hepatotoxicity. On the basis of biochemical studies, the results were found to be significant ($P<0.01$) at a dose of 100 mg/kg body weight of the animals when compared with the standard drug Silymarin (100 mg/kg). Histopathological studies also confirmed the hepatoprotective activity of the *C. moonii* fruits extract.

EP 22 *In vitro* Immunomodulatory Activity of *Psoralea corylifolia Linn.* Seeds on human neutrophils

Deshmukh T. A*., Jawale N.M., Chaudhari R. Y., Patil V. R.

College of Pharmacy, Faizpur, Dist.- Jalgaon (M.S.)

Psoralea corylifolia (Leguminosae), is an erect, annual, 0.6-1.2 m. high, stem and branches grooved, studded with conspicuous glands and with a spreading white hairs found almost throughout India. The seeds are used as diuretic, anthelminitic, and stimulant and recommended in the treatment of leucoderma, leprosy and psoriasis. In China and Malaya, the seeds are regarded as a tonic. It has been found to act as stimulating and tonic nervines. The seed extract has been found to stimulate immune system in mice (Latha et. al.).

In the present study, the seeds of P. corylifolia were collected from the valley of Satpuda and authenticated. The seeds were crushed to obtain required particle size and then subjected to exhaustive extraction with 95% alcohol. The alcoholic extract was fractionated in to Pet. ether, Chloroform and Ethyl acetate.

The total alcoholic extract and each fraction were screened for *in vitro* immunomodulatory activity on human neutrophils using experimental models like Nitroblue tetrazolium qualitative assay, Granulocytes phagocytosis assay, Candidacidal assay and Chemotaxis assay. The total alcoholic extract has exhibited immunomodulatory activity in all parameters studied.

It can be inferred from the study that the total alcoholic extract exhibited more prominent in-vitro immunomodulatory activity in concentration 50 mg/ml and 100 mg/ml.

EP 23 Evaluation of anti-lithiatic activity of ethanolic extract of *Hibiscus rosa-sinenesis* Linn in experimentally induced urolithiasis on albino rats.

Jennifer Fernandes[a], Prasanna Shama, Satyanarayana D, Vijayanarayana K, Karanth K. S.

a. N.G.S.M.Institute of Pharmaceutical Sciences, Mangalore.

This study was investigated the effect fo *Hibiscus rosa* - sinensis linn ethanolic extract as a antilithiatic agent by dissolving preformed kidney stones of calcium oxalate stones in experimentally induced Urolithiasis by administrating sodium glycollate (3%) on albino rats of wister strain. *Hibiscus rosa* sinensis Linn ethanolic extract (150 mg, / 200mg,/ 250mg / kg p.o.) were found to be effective in reducing the kidney stone formation and also in dissolving the preformed stones. Hyper calciuria, Hyper oxaluria are the two parameters considered in the present study for the antilithiatic activity was compared with Cystone® 150mg, 200mg, / 250mg/kg (p.o) a standard marketed ayurvedic formulation of Himalaya drug co. The results suggests that the antilithiatic activity produced by the *Hibiscus rosa* sinensis Linn were significant ($p< 0.01$) in decreasing the elevated levels of excretion of calcium and oxalates in 24hrs urine sample collected after treatment when compared with control and on treatment with standard ayurvedic formulation there exists a highly significant decrease ($p<. 001$) in the excretion rate of calcium and oxalate. There exists a highly significant difference between the groups ($P< .001$). Thus claiming antilithiatic activity, the claim made in the indigenous system of medicine.

EP 24 Hypoglycemic and antihyperlipidemic activity of leaves of *Solanum melongena* Linn. (Brinjal)

Mutalik S[a], Manjula SD[1], Sudheer M, Udupa N

College of Pharmaceutical Sciences, Manipal-576119, Karnataka, India

1. Department of Physiology, Kasturba Medical College, Manipal-576119, Karnataka, India

Solanum melongena Linn. (Brinjal; Solanaceae), a culinary vegetable, has been in use in the Indian system of medicine. The present study was initiated to evaluate the hypoglycemic activity of dry residue of leaf juice of *Solanum melongena* (SM). The leaves were collected in March from the rural areas of Bellary and identified in the Department of Botany, Poorna Prajna College, Udupi. The juice of fresh leaves (yield: 48% w/w) was obtained by trituration followed by pressing the leaves using a tincture press. The yield of the dry residue was 0.62% w/v. SM was subjected to acute (6h) and long-term (30 days) hypoglycemic activity in normal and streptozotocin induced diabetic mice and effect on glucose tolerance. At the end of the treatment period, serum levels of lipid profile (high-density lipoprotein, triglycerides and total cholesterol) and, hepatic glycogen and total protein contents were estimated in diabetic mice. SM produced significant ($p<0.05$) reduction in blood glucose levels in normal and diabetic mice at 250 and 500 mg/kg doses in both acute and long-term studies, which was comparable to glibenclamide. The observed hypoglycemic activity of SM may be due to the presence of flavonoids, alkaloids and tannins whose antidiabetic activity is already well documented. The results of oral glucose tolerance test showed that SM produced significant ($p<0.05$) decrease in blood glucose levels, indicating increased glucose tolerance.

SM treatment significantly ($p<0.05$) increased liver glycogen and protein levels, which could be due to increased insulin release and peripheral uptake of glucose. The elevated lipid profile in diabetic mice was significantly ($p<0.05$) reduced by SM, which could be attributed to the inhibition of endogenous synthesis of cholesterol and enhancement of its excretion through intestinal tract.

EP 25 Studies on the anti-inflammatory activity of 1,3 Aubstituted 4(4-carboxy methylene oxyphenyl) azetidine-2-one derivatives

S. G. TAD*[1], A.V. Yadhav[2], S. Ramachandran Setty[3], B.N. Poul[4], V. N. Karbhari[5], R.K. Jadhav[5] B. V. Yadhav[6]

1. College of Pharmacy, Nilanga
2. Govt. Polytech. , Karad
3. Dept. of Pharmacology) V.L.C.P., Raichur
4. Maharashtra College of Pharmacy, Nilanga
5. Maharashtra College of Pharmacy, Nilanga
6. Poona College of Pharmacy

The literature review indicates that Azetidine and its derivatives have been found effective as Anti-inflammatory agent in addition to many other uses. 4(4-Carboxy Methylene Oxy Phenyl) Azetidine-2-one Derivatives have been synthesized successfully in our laboratories.

The pharmacological screening to established their usefulness as Anti-inflammatory agents, was carried out in present study. At the first place the dose range of these compounds was determined by Blind Screening studies. In addition, safety index was determined by performing the toxicity studies on mice.

In our study the anti-inflammatory activity was studied by inducing inflammation in Albino Rat's hind paw. The effect was measured by using Plethysmograph. The effect was compared with Diclofenac Sodium as a standard anti-inflammatory agent.

Six different substituted Azetidine derivatives have been used in present study. In our toxicological study we found that there was no lethal effect upto 600 mg./kg(max. dose tried). No delayed toxicity was observed in any other groups. The anti-inflammatory activity was studied at the two different doses. i.e., 100 mg / kg & 200 mg / kg

For each substituted derivatives 12 animals in two groups were used for two different doses. For standard drug (Diclofenac Sodium) 35 mg/kg dose was used. All compounds have been shown Anit-inflammatory property comparable to that of standard drug. The compound was produces 25 to 65% reduction in oedema volume in dose dependent manner.

EP 26 Wound healing activity of *Abutilon indicum*

Saleem M.A*, Humera.S, Asgar Ali, Sadath Ali, Roshan S, Jameel Patel

Luqman College of Pharmacy, Gulbarga, Karnataka

To study the effect of alcoholic extract of *Abutilon indicum* on wound healing activity.

Abutilon indicum (Linn) of family Malvaceae is found throughout tropical and sub-tropical region in India. The would healing activity of *Abutilon indicum* was carried out in albino rats. Ethanolic extract of *Abutilon indicum* vacuum dried was tested for various phytochemicals and screened for experiment models which included wound healing activity using incision, excision, and dead space wound at a dose of 400 mg/ kg body weight. The alcoholic extract was selected base on Up and Down method the result of acute toxicity in mice.

As per preliminary phytochemical investigation alcoholic extract shows the presence of alkaloids, glycosides, polyphenolic compounds, flavanoids and steroids. Significant increase in wound contraction rate, skin breaking strength, epithelisation period was observed. Pro healing action seem to be due to increase in collagen decomposition as well as better alignment and maturation.

From the results obtained above it may be concluded that the plant *Abutilon indicum* is endowed with significant wound healing activity, thereby justifying its use in traditional medicine.

EP 27 Pharmacological study of essential oils obtained from *Callistemon citrinus* and *Callistemon lanceolatus*

T. Subburaj, V. Maithili*, Kalakar Bal and B. Suresh

Department of Pharmacognosy, J.S.S. College of Pharmacy, Rocklands, PB. NO : 20, Ootacamund - 643 001, (T.N.)

Aromatic plants contain mostly essential or volatile oil as one of its secondary metabolite which are used for cosmetic and medicinal purposes. Two species of *Callistemon citrinus* and *Callistemon lanceolatus* family Myrtaceae, containing high volatile oil belongs to the same genus of Eucalyptus had been selected. Hence, we were interested to do the pharmacological screening for the volatile oils from the leaves of both the sources obtained by hydrodistillation. In behavioural and acute toxicity

studies, at the end of 4 hour for the essential oil of *C. citrinus*, at a dose of 2000mg/kg all the mice were found to be dead and at 1900mg/kg only 50% mortality occurred. The essential oil of *C. lanceolatus* at the end of 4 hour at 300mg/kg, all the mice were found dead and at 700mg only 50% mortality occurred. No mortality was seen at the end of 72h, with 1800mg/kg in *C. citrinus* and 600mg/kg in C. lanceolatus. The anti-inflammatory activity of the essential oils were studied by Carrageenin induced rat paw edema method using Ibuprofen as standard. The % protection at the end of 1 hour was found for various doses. At 100mg, 200mg and 300mg/kg of the essential oil of *C. citrinus*, the % protection were 74.2, 77.4 and 83.9% respectively. For C. lanceolatus the % protection at 40, 70 and 140mg/kg were found to be 67.7, 75.8 and 87.1% respectively. Ibuprofen, a standard showed 90.3% protection for the same. The essential oils of both the species showed C.N.S. effect and anti-inflammatory activity.

EP 28 Topical anti-inflammatory studies of *Saussurea lappa* and *Tephrosia purpurea* using Laser Doppler flowmetry

Smitha Gopi *, Jadhav S.R., Mukherjee S.A., Suresh Kumar P., Trivedi C.A. And Saraf M.N.

The Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai - 98

Ethanolic extracts of roots of *Saussurea lappa* (Fam-Compositae) and the aerial parts of *Tephrosia purpurea* (Fam-Fabiaceae) have shown the inhibition of mast cell degranulation in mice and antiinflammatory activity in rats. The present study was carried out for evaluation of topical antiinflammatory activity of the ethanolic extracts on healthy human volunteers.

Laser Doppler Flowmetry constitutes a method for continuous and non-invasive recording of cutaneous blood flow. The present investigation was carried out on 6 healthy volunteers. The extracts were incorporated into gel base so as to form a 10 % gel. Basal blood flow response was measured for 10 min before and after application of the formulation. Hyperaemia was produced using 20 ml of 0.5 % w/v methyl nicotinate with contact time of 4 min. The hyperaemic response was recorded for 30 min. The above process was repeated after occlusion by formulation or gel base for 1 hr. Diclofenac gel was used as a reference standard.

AUC and percentage inhibition of hyperaemia due to the formulation were calculated. Gel formulation of ethanolic extract of *Saussurea lappa* (10 %) and *Tephrosia purpurea* (10 %) showed 60 % and 35 % inhibition of hyperaemia induced by methyl nicotinate respectively. Thus it can be concluded that both the plants produce topical antiinflammatory activity.

EP 29 Free radical scavenging activity of arthritin on arthritic rats

S.L. Raja Sekhar Karna, E. Meignanam D. Chamundaswari, V. Vaijayanthi S. Uma Maheswari, C. Gandhimathi, J. Vasantha

Sri Ramachandra College of Pharmacy, Sri Ramachandra Medical College and Research Institute (DU), Porur, Chennai-116.

Arthritin is a polyherbal formulation consisting of *Acacia arabica, Withania somnifera, Juniperus communis, Asparagus racemosus, Tinospora cordifolia, Tribulus terrestris, Anethum sowa, Curcuma zerumber, Zingiber officinalis* has been studied for free radical scavenging activity in male arthritic rats. Arthritis was induced by intradermal injection of 0.1ml of complete Freund's Adjuvant in right hind paw of rats. One group maintained as positive control.

On the 11th day onwards the herbal formulation was at dose of 0.5g/kg and 1g/kg p.o. respectively for 8 days to group III & IV. The paw volume was measured periodically on 0, 7, 11 and 18th days.

On the 19, blood was withdrawn from all rats and biochemical estimations like lipid peroxidation, total reduced glutathione, glutathione peroxidase, super oxide dismutase were studied in the plasma/ haemolysate.

The knee and ankle joints of all rats were subjected to histopathological investigation. Group-I was maintained as normal control. There was significant reduction in the paw volume of the arthritin treated rats when compared to positive control (Group II).

A significant reduction of lipid peroxidation and increase in total reduced glutathione, superoxide dismutase and glutathione peroxidase were observed in drug treated groups (III&IV) compared to positive control (Group II).

The results showed a dose dependent response in drug treated groups. Further his topathological investigation also supported the above results.

From the above studies, it can be concluded that the poly herbal formulation Arthritin has a major role in reducing inflammation in arthritic condition through free radical scavenging mechanism.

EP 30 Evaluation of hepatoprotective activity of *Cheledonium majus* in homoeopathic dosage forms

Sadhana Sathaye*, A.R. Juvekar, Anagha Borwankar

Pharmaceutical Division, Institute of Chemical Technology, University of Mumbai, Mumbai - 400019.

Homoeopathic dosage forms constitute a major share in alternative medicinal therapy. But, its activity need to be evaluated scientifically to endorse its usefulness in treating various diseased conditions. *Cheledonium Majus* is a drug which is homoeopathic dosage forms its used mainly to treat various liver disorders like hepatitis, jaundice, liver cirrhosis etc. The drug is being used clinically by homeopathic physicians over no. of years with good success.

The investigation deals with preclinical evaluation of hepatoprotective potential of *Cheledonium Majus* in homoeopathic dosage forms. Alcohol 6% v/v was used to produce liver toxicity and certain marker liver enzymes were used as parameters to evaluate the efficacy of *Cheledonium Majus*. The results indicated significant curative activity after alcohol induced liver damage, reconfirming its clinical use.

EP 31 Anti-Ulcer activity of *Asparagus racemosus* Wild. In stress induced ulcerative model

Siddhraj S. Sisodia *, Maheep Bhatnagar[1], Mahendra S. Ranawat, Yuvraj S.Tanwar.

Dept. of Pharmacology, B. N. College of Pharmacy, Udaipur (Raj.) India.

1. Cellular and Molecular Neurobiology Lab., Dept. of Zoology, University College of Science, M. L. Sukhadia University, Udaipur (Raj.) India.

The present study was undertaken to study the anti-ulcer activity of *Asparagus racemosus* (shatavari) and its action against stress induced gastric ulcer. Gastric ulcer disease is one of the common disease. Effect of *Asparagus racemosus* (Shatavari) crude extract in gastric ulcer model was studied. *Asparagus racemosus* crude extract (50 mg/ Kg/ day p.o.) was given for six days. On seventh day pyloric ligation was performed for the collection gastric fluid. Drug treatment gives significantly reduced in stress (restraint stress) induced gastric lesions as compared to a standard anti-ulcer drug Ranitidine (30 mg/ Kg/ day p.o.).

Asparagus racemosus (Shatavari) produced significant reduction in volume of gastric secretion, free acidity, total acidity, ulcer index and significant increase in total carbohydrate and total protein ratio and pH of gastric juice.

Asparagus racemosus proved to be an effective antiulcerogenic agent, whose activity can well be compared with that of Ranitidine hydrochloride. There is possibility that shatavari causes inhibitory effect on release of gastric hydrochloric acid in stress induced gastric ulcer and it protects gastric mucosal damage. Such protective action may because of their antioxidant properties or may be due to increase of the release of gastro protective prostaglandin's (PG).

EP 32 Antiulcerogenic effect of *Selenomethionine* against experimentally induced gastric ulcer in rats.

[a]Ronald Fernandes*, Yogendra Nayak, Vijayanarayana, [b]Krishna Moorthy,

a. N.G.S.M.Institute of Pharmaceutical Sciences, Mangalore. bmangala Gangotri, Mangalore University, Mangalore

This study was designed to determine the ulcer protecting effects of selenomethionine against gastric lesions induced by 50% ethanol, the experimental related to lesion pathogenesis with production of reactive species. The levels of thiobarbituric acid reactive substances (TBARS, as index of lipid peroxidation) were determined. Pretreatment with a dose of selenomethionine (4mg/kg i.p.) 2 hr before administration of 50% ethanol resulted in the most effective necrosis prevention. TBA reactive substances in the gastric mucosa were increased by ethanol injury and this increase was inhibited by the administration of selenomethionine. Selenomethionine caused significant reduction in ulcer index. These results suggest that the gastro protective effect of selenomethionine in this experimental model appears through an anti lipoperoxidant effect.

EP 33 Anti-inflammatory activity of leaf volatile oil of *Atalantia monophylla* Correa

S. Manimaran, Anil Kumar, L.Parul*, G.Vaibhav, K.Kripesh, Sunil Sharma and B. Suresh

Department of Phytopharmacy & Phytomedicine, Tifac Core HD, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu.

The plant *Atalantia monophylla* Correa is s shrub or tree let about 6 mm tall belongs to the family Rutaceae[1]. The berries of this plant yield warm oil, which is used in native medicine considered as a valuable application in chronic rheumatism and paralysis.[2] Constituents of leaf volatile oil is sabinene, alpha terpinene, decana, terpenene-4-ol and methyl eugenol etc. The anti- inflammatory activity of leaf volatile oil of *Atalantia monophylla* Correa was carried out. The volatile oil was distilled from the leaves by hydrodistillation method. The distilled oil was subjected to anti - inflammatory activity. The oil (100 mg/kg) possesses significant anti - inflammatory activity against carrageenin induced hind paw oedema model compared to that of standard drug infomethacin (10 mg/kg).

EP 34 Inhibition of lipid auto-oxidation of rat liver microsomes by *Decalepis hamiltonii* root extract

Yougendra Nayak*†, M. Lakshmana†, Shylaja M. Dharmesh†, Harish Nayaka†

N.G.S.M. Institute of Pharmaceutical Sciences, Nantoor, Mangalore

Decalepis hamiltonii. W&A. (Family: Asclepiadaceae) is locally known as *Mavali khizangu* (Tamil) commonly available at Karnataka, Kerala and Tamilnadu. It is highly consumed in South India; the roots are pickled as such or with lime. The root extract was been used as the substitute for the well-known Ayurvedic drug Sariva (*Hemidesmis indicus*), which is mainly used for agnimandya (loss of appetite), aruchi (distaste), kasa (cough), swasa (dyspnoea), jwara (fever), *raktapradhara* (menorrhagia), varakta (type of arthritic disorder) and *raktashodhaka* (blood purifier) in skin diseases. The roots contain mainly vaniline (0.45%) and other volatile constituents (0.68%) along with some polyphenols. Thus the herb was found to be of extensive medicinal importance.

The water extract of the root was prepared and standardized depending on the total protein and polyphenol content. Preliminary antioxidant activity was assessed by *in vitro* biochemical assays like Reducing power assay, DPPH assay and Hydroxyl radical scavenging assay. Results were found to be highly significant at ì gm concentration of the extract. Further work was carried out to see the inhibition of lipid auto-oxidation of rat liver microsomes. The extract shows significant protection of lipid auto-oxidation (±70%) at ì gm concentrations.

These results indicate that *Decalepis hamiltonii* water extract has a potential role in free radical scavenging and inhibition of lipid peroxidation. Further the phytochemical work is going on for mechanistic approach of pharmacological activity. The proposed work also includes the beneficial activity of this herb in chemoprevention of stress induced ulcers, hepatotoxicity, carcinogenesis and cancer metastasis.

EP 35 Anti-ulcer activity of methanolic extract of *redia floribunda*

K. Hemamalini, K.Umasankar, M.Shiva Kumar,P. Sridevi, M.Vimal Kumar Varma.

Smt. Sarojini Ramulamma College Of Pharmacy, A.P Periya College of Pharamaceutical Science, For girls, Trichy.

Methanolic extract of *Redia floribunda* was found to posses significant anti ulcer activity against asprin, indomethacin, alcohol and stress induced ulceration in experimental animal models . Significant inhibition was also observed in asprin induced gastric ulceration and secretion in pylorus ligated rats. The lipo oxygenase inhibiting, histamine antagonist and antisecretory effects of the extracts could probably contribute towards anti ulcer activity.

Redia floribunda may be considered to be a drug of natural orgin which possess both inflammatory and anti ulcer activity.

EP 36 Anti-inflammatory activity of extracts of leaves of *Garcinia xanthochymus,* family-*Guttiferae*

Nirmal Sunil, Subhash Ch. Mondal, S.C. Pal, P.S. Borhade, D.P. Belasare, V.A. Bairagi***

N.D.M.V.P. Samaj's College of Pharmacy, Gangapur Road, Nasik-2.

Pharmaceutical Technology, Dept. of Pharmacy, Jadavpur, Kolkata-32.

Garcinia xanthochymus, family- Guttiferae, is a medium ranged bushy evergreen tree with a straight trunk and angular spreading branches. The tree is widely distributed in the lower hill forest of eastern Himalayas, Assam, Mumbai, Madras, Mysore and from Travancore to Cochin. Therapeutically dried fruit is given in bilious condition. Also raw fruit is used to remove Vata and Kapha. Ripe fruit juice is useful in destroying tridosha and is good in heart complaints and biliousness.

The leaves were collected and sun dried. It was powdered and subjected to successive extraction with petroleum ether (60-80oc), methanol and ethyl acetate.

Crude petroleum ether extract, crude methanolic extract and crude ethyl acetate extract of leaves of G. xanthochymus (100mg/kg), including known anti-inflammatory drug, ibuprofen(100mg/kg) were administered orally to albino rats (100-150gm) 1 hr prior to induction of edema. Edema is induced by injecting 0.1 ml carrageenan suspension (1%) subcutaneously into sub plantar tissue of hind paw. The inflammation was evaluated by monitoring paw edema as volume measured by mercury displacement method.

Statistical analysis was carried out using student's t-test (unpaired).

The results demonstrated that the %inhibition of paw edema by petroleum ether extract, alcoholic extract and ethyl acetate extract were 63%, 60% and 56% respectively, as compared to 69% inhibition of paw edema by ibuprofen. The equivalent % inhibition of petroleum ether extract, alcoholic extract and ethyl acetate extract is 91.3%, 86.96% and 81.16% compared to standard drug ibuprofen.

In conclusion the petroleum ether extract of leaves of G. xanthochymus exhibited more anti-inflammatory activity than methanolic extract and ethyl acetate extract and suggesting that the extract is worth examine further to isolate the active constituent responsible for this activity.

EP 37 Estimation of hydroxyproline in granulomatous tissue in dead space wound model

Amit Kale*[1] and Bhise S.B.[2]

1. Pharmaceutical Dept, Mumbai University Institute of Chemical Technology, Matunga, Mumbai.
2. Govt. College of Pharmacy, Aurangabad.

Now-a-days a lot of research is going on wound healing including mechanisms of wound closure, endogenous and exogenous factors affecting on same and drugs from all around the branches of medicinal systems. The drugs used for treating wounds act by various mechanisms, such as growth factor suppliers, or stimulators, granulations tissue promoters, collagen synthesis enhancers, anti-infectives, inducers of enzymes required for cross-linking of collagen molecules. The effectiveness of new molecule in treatment of wound is assessed by various methods. Hydroxyproline is an amino acid present in the collagen fibres of granulomatous tissue. It's estimation in the region of wound helps clinically to understand progress rate at which the healing process is going on in the connective tissue of the wound. In our study, we formulated Chitosan gels (2%) to assess wound healing activity of Chitosan (model drug) using dead space wound model. The animals selected were healthy Wistar rats. The dead space wounds were made according to the procedure followed by Ehrlich and Hunt. The animals were divided into two groups: one control (C) and other drug treated group (D), each containing 6 animals. The parameters studied after 10th post wounding day were determination of hydroxyproline in granulomatous tissue and histopathological study. Hydroxyproline in the newly developed granuloma was determined using validated colorimetric assay. The results obtained were compared with histopathological study. It was found that estimation of hydroxyproline in newly formed granulomatous tissue is simple, easy and predictive tool that gives an idea about the rate at which wound healing process is going on along with the collagen content and henceforth the usefulness of newer moieties invented for wound care.

EP 38 Investigation of *in-vivo* and *in-vitro* interactions of drugs used during operative procedures

Oak Mayura, Vador Nimish *, Jagtap A G.

The Bombay College of Pharmacy, Kalina, Santacruz(E), Mumbai-400 098

An array of drugs works in tandem to facilitate the surgical procedures. A well-chosen premedication coupled with an appropriate anaesthetic will decrease anxiety and result in much more comfort to the patients.

Neuromuscular blockers are administered routinely during intubations, surgeries, orthopedic manipulations and brief invasive procedures to facilitate intubation and maintenance of muscle relaxation. H_2-receptor antagonists (cimetidine, ranitidine etc.) are used for decreasing gastric volume and increasing the pH of gastric contents so as to reduce the occurrence of aspiration pneumonia, oesophagitis and Mendelson's syndrome.

There is possibility of interactions among pre-anaesthetic medicaments and commonly used anaesthetic drugs such as lignocaine and ketamine in patients receiving H_2 receptor antagonists and neuromuscular blockers as pre-anaesthetic medicaments.

Present study was designed to elucidate the potential interaction of cimetidine with neuromuscular blockers such as pancuronium and anesthetics such as lignocaine and ketamine. The *in vitro* procedures were used to analyze the action of cimetidine as prototype H_2 receptor antagonist on skeletal muscle preparation and neuromuscular junction. Also, they were designed to analyze the effects of cimetidine on lignocaine, ketamine and pancuronium induced skeletal muscle relaxation. To support the findings, in-vivo tests, such as rotarod and inclined plane tests, were carried out. Results were analyzed by Student's 't' test at $p < 0.05$.

It was observed that cimetidine significantly antagonized the lignocaine, ketamine and pancuronium induced skeletal muscle relaxation *in vitro*, but significant increase was observed in duration of action of anaesthetics *in vivo* while no significant effect was observed on onset and duration of action of pancuronium.

EP 39 Antimicrobial activity of n-hexane and Alcohol extracts of stems of *Dendrophthoe falcata* Linn family Loranthaceae

Borhade P.S*, Nirmal Sunil, Bhambar R.S, Pal S.C.

*College of Pharmacy, Nashik-422002.

Dendrophthoe falcata is an evergreen shrubby, parasite distributed in tropical and subtropical region of World. In Ayurveda it is mentioned to use in Kapha and Pitta conditions. It is used in following conditions - in treatment of pulmonary tuberculosis, asthma, menstrual disorder, swelling, wounds, ulcer, renal and vesicle calculi. It is also used as a bitter, astringent, aphrodisiac, narcotic and diuretic. Antimicrobial activity

of n-hexane and alcoholic extract of stem of *D.falcata* was tested on various strains of pathogenic bacteria. The Kirby Bauer disk diffusion method was employed for antimicrobial testing of extracts. *Staphyl. occous aureus* ATCC 29737 and *E.coli* ATCC10536 were used as control strains. The strains of bacteria used for antimicrobial activity were *S.aureus* laboratory strain, *S.citrus, S.albus, Corynebacterium diphtheriae* from Gram positive group and *Shigella boydii, Salmonella typhi* and others from Gram negative group.

From the observations it was found that the n- hexane and alcohol extract of stem of the *D.falcata* was effective against *S.aureus, S.citrus, Corynebacterium diphtheriae* and *Shigella boydii,* hence it was concluded that Gram positive group bacteria were very susceptible than that of Gram negative bacteria.

EP 40 Pharmacodynamic studies of valdecoxib and β-Cyclodextrin inclusion complex

Jadhav G.S.*, Sonaje G. and Vavia P.R.

Pharmaceutical Division, University Institute of Chemical Technology, Matunga, Mumbai - 400 019.

The study involved evaluation of valdecoxib and β-Cyclodextrin Complex for their anti-inflammatory and analgesic activity. The inclusion complex of valdecoxib with β-Cyclodextrin (BCD) was prepared using the freeze drying technique.

Carragenan induced rat paw oedema model was used to evaluate the anti-inflammatory activity of these complexes. The inflammation in rat paw was produced by injecting 0.1 ml carragenan (1% w/v solution) subplantarly. Oral doses of valdecoxib complexes were administered before injection of carragenan and inflammation produced was measured plethysmometrically at various time intervals.

The analgesic potential of the complexes was assessed using acetic acid induced writhing response. A suspension of drug or complex was administered orally. After various time intervals acetic acid (0.7%, 10 ml/kg) was injected intraperitoneally. The numbers of withes were counted for 15 mins.

The inclusion complexes of valdecoxib showed higher anti-inflammatory activity than pure valdecoxib suggesting faster drug absorption and better bioavailability. The best analgesic activity was observed at 8 mins. for the complex and 29 mins. for pure drug. This suggests that the onset of action was faster in case of cyclodextrin complex of valdecoxib.

EP 41 Effect of chloroform extract of *Desmodium gangeticum* on mast cell degranulation

M. V. V. Prasad [1]*, T. V. Narayana[1] and K. Balakrishna[2]

1. Dr. H. L. T. College of Pharmacy, Bangalore - 571 502.
2. Central Research Institute for Siddha, Chennai - 600 108.

Desmodium gangeticum (Linn) DC. belongs to the family Leguminosae. It is found in the lower Himalayan region and throughout the plains of India. It is used in the indigenous system of medicine. The drug is said to be useful in asthma and other chest ailments. The effect of the extract on mast cell degranulation (*in vitro* study) was carried out by the modification methods of Kaley and Weiner. Under the experimental conditions about 24% of mast cells are normally degranulated. The mast cell degranulater, compound 48/80 (p-methoxy-N-methyl phenethylamine) produced about 57% of degranulation. Pretreatment with the chloroform extract of *Desmodium gangeticum* had shown a significant protection against the degranulation induced by compound 48/80. The protection was also evidenced by pretreatment with disodium chromoglycate a potent mast cell stabilizing agent.

EP 42 Evaluation of anti-obesity effect of polyherbal formulation NR/AOB/27 in atherogenic and cafeteria diet fed rats.

C. Devaraja, Raju B. Koneri*, Kevin N. Patel, H.J. Hrishikeshavan.

Department of Pharmacology, Visveswarapura Institute of Pharmaceutical Sciences, Rajiv Gandhi University of Health Sciences, Bangalore-24.

Obesity is now a days a common and challenging health problem. It is not only a problem in itself but also a predisposing factor for many other adverse health out comes like non-insulin dependent diabetes mellitus (NIDDM), atherosclorsis, dyslipidemia, cardiovascular disorders etc. The present study was undertaken to evaluate anti obesity effect of polyherbal formulation NR/AOB/27.

NR/AOB/27, a polyherbal formulation of natural remedies private limited, Bangalore, containing 50% alcoholic extract of *Cyperus rotundus* roots (Cyperaceae), *Mangifera indica* bark (Anacardiaceae) and aqueous extract of *Salacia oblonga* roots (Celastraceae)

The experimental design of present investigation was carried out in the following regimen, 36 female albino rats Wister strain; weighing 100-150 were equally distributed in to 6 groups. Group I-Received normal feed and water ad libitium, Group-II Received normal feed and NR/AOB/27,Group III-Received atherogenic diet, Group IV-Received the atherogenic diet and NR/AOB/27,Group V-Received the cafeteria diet, Group VI-Received the cafeteria diet and NR/AOB/27.The experiment was carried out for 40 days. NR/AOB/27 was administered orally in a dose of 400mg/kg/.,p.o.,once a day for 40 days. This dose was selected on the basis of our preliminary studies.

There was significant ($p<0.01$) reduction in body weight, internal organ and fat pad weight, serum glucose, total cholesterol, triglyceride levels and increase in body temperature and locomotor activity after treatment with NR/AOB/27 in atherogenic and cafeteria diet fed rats. From this study we can conclusively state that NR/AOB/27 is a potent anti obesity drug. Further pharmacological and biochemical investigations are underway to elucidate the mechanism of anti-obesity effect of polyherbal formulation.

EP 43 *In-vitro* free radical scavenging activity of essential oils of nilgiris

Ashok G, Vijayan P, Raghu C, Jagadish P.C.*, Sameer P and Suresh B.

J.S.S College of Pharmacy, Ootacamund, Tamil Nadu

The essential oils being one of the important secondary metabolites of plants are used for medicinal and cosmetic purposes. They are used as perfuming, flowering and as therapeutic agents in Pharmaceutical preparations. Essential oils from *Ocimum sanctum* (aerial part), *Artemescia nilagara* (leaves), *Artemescia pellens* (leaves and flowers), *Geranium* (whole plant), *Java curonella* (seeds), *Myristaca fragrans* (cornels) and *Acorus calamus* (rhizomes) was extracted by hydrodistillation.

All the seven essential oils were screened for *in-vitro* tree radical scavenging activity using 1.1-Diphenyl-2-picryl hydarzyl (DPPH) and Nitric Oxide models. Rutin and Ascorbic acid were used as standards for comparison. The results were expressed as IC_{50} values - SE.

All examined essential oils were able to reduce DPPH radicals into the neutral DPPH-H form and this activity was dose-dependent. However, only *Ocimum sanctum* oil showed potent inhibition with IC_{50} value 32 = 2.63 µg/ml as compared to 43.6 =1.79 and 18.17 = 1.79 of standards rutin and ascorbic acid respectively. All the other oils showed moderate activity.

Ocimum sanctum and *Myristaca fragrans* oils exhibited potent nitric oxide radical inhibition activity with IC_{50} values 123.6 = 2.64 and 133.16 = 2.8 respectively, as compared to 186.5 = 20.85 µgml of standard rutin.

EP 44 Anti-ulcer activity of (Bhasma) *Musa paradisiaca* Linn., and *Zingiber officinale* Rosc., in experimentally induced gastric ulcers in rats

Elango. K., Johnson K. Mathias, Subburaju, T[1]., Sivakumar S*, and Suresh. B.,

Dept. of Pharmacology, J.S.S. College of Pharmacy, Ooty, Tamilnadu - 643001

'Peptic ulcer' refers a group of ulcerative disorders of the upper gastrointestinal tract, which appears to have common role to play in the participation of acid-pepsin in their pathogenesis. Peptic ulcer is mainly a disease of adult males and it does not appear to depend on any clear factor, but it is initiated by stress conditions occurring over long periods. In the present study two herbal preparations were examined for the anti ulcer activity. The study involved usage of ash obtained from *Musa paradisiaca* Linn (Bhasma) (20 mg/Kg) and ethanolic extract of *Zingiber officinale* Rosc. (19 mg/Kg) The above preparations are screened for gastric anti ulcer activity by modified pylorus ligated (Shay) rat model and Aspirin plus modified pylorus ligated (Shay) rat model. The herbal preparation showed decrease in the free acidity, total acidity pepsin and total protein content and significant increase in total carbohydrate - protein ratio. Both the preparations strengthened the defensive factors than producing anti secretary effect. This shows that both models act by cytoprotective activity.

EP 45 Spermicidal and antiulcer studies on *Hyptis sauveolens poit* in albino rats

P. Venkatesh*, S.N. Pandeya, Srivstava R.S.

Department of Pharmaceutics, Banaras Hindu University, Varanasi and Department of Pharmacy of Allahabad Agricultural Institute, Deemed University, Allahabad.

Hyptis sauveolens poit folk medicinal plant used by the tribals in the Indian system of medicine. Based on the literature review, it is found that the infusion of the plant is used in catarrhal conditions, affections of the uterus, gonorrhoea and conjuctivities. From times immemorial the phenomenon of peptic ulceration posed a major clinical problem and for many years. Research in the field of fertility regulation has been directed mainly towards developing methods for females contraception. In the present we attempted to study the antiulcer and spermicidal activities in albino rats. *Methyl betulinate* (Isolated constituent), petroleum ether extract and ethonolic extract of aerial parts of the plant were screened for their anti ulcer and spermicidal activities. The antiulcer activity against aspirin (Dispirin, Reckitt and colman) induced ulcers and compared with the activity of ranitidine (Zinetae, Glaxo) for administration by gavage, each

compound was mixed equal amount of sodium carboxy methyl cellulose and suspended in distilled water. For spermicidual activity sperm motility sperm viability and sperm count methods were screened.

Petroleum ether extract showed equiprotection against aspirin induced gastric ulcers as ranitidine and methyl betulinate also showed protection. The activities were further confirmed by histological studies by using haemooxylin and eosin stains. A marked increase in taking up of the haemotaxylin-Eosin stain, in methyl betulinate and Pet. Ether extract treated groups of rats. A significant decrease in the sperm motility, sperm viability and sperm number was noted in ethanolic extract whereas in methyl betulinate and petroleum ether extract insignificant changes were noted.

EP 46 Effect of grape seed oil (GSO) on carbontetrachloride (CCl_4) induced liver damage In male Albino rats.

Uma Maheshwari. M*[1] and Padma G.M. Rao[2].

1. College of Pharmacy, Sri Ramakrishna Institue of Paramedical Sciences, Coimbatore - 641 044.
2. KMC, Manipal, Karnataka

Grape seed oil is obtained from grapeseeds after the wine pressing. It has a very high level of anti - oxidant vitamin E (60 - 120 mg/100g), which makes the oil very stable. The anti-oxidant property is claimed to be the mechanism of hepatoprotective activity. Based on this, the present work was undertaken. The study was an attempt to assess the hepatoprotective effect of grape seed oil (GSO) against carbontetrachloride (CCl_4), a well known hepatotoxin. The hepatoprotective activity was evaluated on the basis of biochemical parameters (AST, ALT and ALP levels) and histopathological studies. The probable mechanism of action was studied by estimating malondialdehyde (MDA), glutathione (GSH) and protein concentratin. There was a significant increase in serum enzymes and MDA levels and a decrease in GSH and protein concentration which were reversed with GSO. The above studies suggest that GSO offers vast possiblities in the treatment of various liver disorders. This may be due to the very high level of anti - oxidant vitamin E, which was claimed to be the mechanism of hepatoprotection. Further studies on other models and extensive clinical trials are needed to confirm these findings.

EP 47 Hepatoprotective and antioxidant effect of *Hemidesmus indicus* (L.) R.Br

G. M. M. Rao*, M.V.Kumar, R. Govindarajan, M.M. Pandey, Ch. V. Rao, A. K. S. Rawat, and S. Mehrotra**

Pharmacognosy and Ethnopharmacology Division, National Botanical Research Institute, Lucknow-226 001

Since ancient times, plants have been an exemplary source of medicine. Ayurveda and other Indian literature mention the use of plants in treatment of various human ailments. India has about 45000 plant species and among them, several thousands have been claimed to possess medicinal properties. Research conducted in last few decades on plants mentioned in ancient literature or used traditionally for liver disorders have shown hepatoprotective activity.

The present study was undertaken to investigate the relationship between liver protective effects and antioxidant activity of the dried roots of *Hemidesmus indicus* (L.) R.Br, (an indigenous plant used in Ayurvedic medicine in India) in carbontetrachloride-induced hepatic damage in rats. The 50% ethanolic extract of *Hemidesmus indicus* (L.) R.Br roots inhibited the formation of oxygen derived free radicals (ODFR) invitro with IC_{50} of 560 mg/ml, 680 mg/ml and 600 mg/ml (Fe^{2+}/ascorbate system), 970 mg/ml (Fe^{3+}/ ADP/ ascorbate system)for superoxide free radical production, hydroxyl radical generation, nitric oxide radical formation and lipidperoxidation formation, respectively. The oral administration of the extract (200 and 400 mg/kg) significantly reduced carbon tetrachloride induced hepatotoxicity in rats, as judged from the serum marker enzymes glutamate oxaloacetate transaminase (GOT), glutamate pyruvate transaminase (GPT) and alkaline phosphate (ALP). These results were comparable with those obtained with quercetin (100mg/kg, p.o). Based on these findings we may suggest, that the liver protective and antioxidative effects of *Hemidesmus indicus* (L.) R.Br possibly involve mechanisms related to free radical scavenging effects. The results indicate that the roots of *H. indicus* possess significant hepatoprotective and anti-oxidant properties.

EP 48 The effect of chlorpromazine on 5-Ht induced colonic secretion in anaesthetized rats and diarrhoea in mice

Pramod C. Gadad*, B. M. Patil[1], S.V. Aladakatti[2]

Department of Pharmacology, K.L.E.S's College of Pharmacy, Belgaum, Karnataka

The effect of chlorpromazine on 5-HT induced fluid and chloride secretion in colon of anaesthetized rats and 5-HT induced diarrhoea in mice was investigated. Subcutaneous administration of 5-HT (6 mg/kg) stimulated fluid and chloride secretion in rat colon. Pre-treatment of rats with chlorpromazine (0.1, 1, and 10 ìmol/kg, s.c.) dose dependently reversed the 5-HT induced fluid and chloride secretion, whereas chlorpromazine (0.1, 1, and 10 ìmol/kg, s.c.) had no effect on basal fluid and chloride absorption in rat colon. Subcutaneous chlorpromazine (0.5-3 mg/kg) dose dependently protected mice from 5-HT (1mg/kg,

i.p.) induced diarrhoea; maximum protection (100%) was observed with 3mg/kg. These results indicate that, though 5-HT induced colonic secretion involves different subtypes of 5-HT receptors but may have common effector pathway of secretory response and this pathway may be sensitive to chlorpromazine.

EP 49 Evaluation of anti-obesity effect of polyherbal formulation NR/AOB/26 in atherogenic and cafeteria diet fed rats

Kevin N.Patel , Raju B.Koneri, C.Devaraja, H.J. Hrishikeshavan and Kamal Modh*

Department of Pharmacology, Visveswarapura Institute of Pharmaceutical Sciences, Rajiv Gandhi University of Health Sciences, Bangalore-24.

The anti obesity effect of polyherbal formulation in female rats fed on cafeteria diet (highly palatable, energy rich animal diet that includes a variety of human snack foods) and atherogenic diet (containing cholesterol 1%, cholic acid 0.5 % and lard oil 5%) for 40 days is studied in the present study. The polyherbal formulation contained mixture of standard extract of *Commiphora mukul* gum (15.7 %), standard extract of *Gymnema sylvestre* leaves (15.7 %) and 50% alcoholic extract of Cyperus rotundus roots (21 %). The polyherbal formulation was administered at a dose of 400-mg/kg., p.o.,per day to the drug treatment groups. The effect of polyherbal formulation on following parameters was recorded body weight, rectal temperature, internal organ and fat pad weights, locomotor activity and various biochemical parameters like serum glucose, total cholesterol and triglyceride levels. There was a significant ($P<0.05$) reduction in body and fat pad weights and significant increase in body temperature after treatment with polyherbal formulation in cafeteria and atherogenic diet fed rats. Treatment with polyherbal formulation also significantly ($P<0.01$) decreased triglyceride and total cholesterol levels in cafeteria and atherogenic diet fed rats. The results of this study suggest that our polyherbal formulation is a potent anti obesity agent and there is a great scope of further research.

EP 50 Inhibited tissue repair in Ta-treated diabetic rats is explained by role transcription factors

***S. S. Devi, And H. M. Mehendale.**

Department of Toxicology, The University of Louisiana at Monroe, Monroe, LA, 71209, USA.

An ordinarily nonlethal dose (300 mg/kg) of thioacetamide (TA), caused 90 % mortality in type I diabetic (DB) rats primarily due to inhibited hepatic tissue repair. The objective of this study was to test our hypothesis that DNA-binding of transcription factors like NF-kB, STAT-3, and AP-1 plays an important role in inhibited hepatic tissue repair in diabetic condition.

We found lower NF-kB binding to nuclear DNA in the diabetic liver. To probe why this inhibition occurs in DB rats, we measured I-kBa, the endogenous inhibitor of NF-kB in cytoplasm. Immunoblot analysis showed that degradation of I-kB in DB rat liver is much lower, indicating inhibited dissociation of NF-kB/ I-kBa complex in the cytoplasm, leading to lower nuclear translocation of NF-kB. Inhibited dissociation of NF-kB/ I-kBa complex is, in turn, due to down regulated phosphorylated as well as total I-kB (IKK) enzyme, which dissociates the complex. Investigation of EGFR/ MAPKs pathway, which is known to facilitate dissociation of NF-kB/ I-kBa complex, revealed down regulation of EGFR, and total as well as phosphorylated MAPKs (ERK1, ERK2 and p38) in the DB rats.

NF-kB/DNA binding results in transcription of cyclin D1, which in association with cdk4 stimulates hepatocytes to progress from G1 to S phase of the cell cycle. Western blot analysis showed that cyclin D1 as well as cdk4 were downregulated in DB rats. STAT-3, which transcribes inhibitory proteins of cyclins, was upregulated in DB rats, suggesting the role of STAT-3 transcription factor in downregulation of cyclin D1 in DB rats.

Overall, these findings suggest that inhibition of transcription factors, regulated by EGFR/MAPKs pathway plays critical role in inhibited tissue repair in DB rats. (Supported by Kitty DeGree Endowed Chair and LBRSF)

GP$_1$ Compatibility and interaction studies in solution of ampicillin trihydrate, sulbactum sodium and ciprofloxacin hydrocholride using the technique of solution calorimetry

Namdev Kashid and Renu Chadha

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh 160014, India.

Many pharmaceutical dosages forms are available containing the combination of α-lactam antibiotics and α-lactamase inhibitors to obtain better therapeutic effects. Resistance of many species of bacteria to α-lactam antibiotics is mediated via inactivation by α-lactamase which can irreversibly bind to â-lactamases and thus prevent the destruction of active α-lactam antibiotics. Also their combination with cirpofloxacin have been used in cancer chemotherapy. Sulbactam significantly increases the bioavailability and absorption of oral ampicillin when the two drugs are administered in the form of the prodrug sultamicillin and it does not interfere with the kinetics of intravenous ampicillin. But drug interactions may occur in these combined dosages forms outside or inside the body in terms of different properties like physicochemical, pharmacological and pharmacodynamic. The excess molar enthalpy of solution of binary and ternary systems of Ciprofloxacin hydrochloride (CP) with Ampicillin trihydrate (AMP), Sulbactum sodium (SS) have been studied to determine any specific or non-speciifc interactions in aqueous solution (pH 2-9) using solution calorimetry. The excess molar enthalpy of solution value for binary mixtures AMP:SS indicates less interactions in solution. However, the much higher and negative value for the binary and ternary system containing ciprofloxacin does not rule out any chemical interaction between components. The study indicates that ciprofloxacin hydrochloride should not be prescribed with above mentioned drugs due to incompatibility in solution.

GP$_2$ A new sensitive, validated method for the quantitative analysis of tablets by using near infrared spectrophotometry (NIR)

M. G. Pai*, Aarti Naik, Dattesh Verlekar, Venkateshwarlu K., Yogesh Naik.

Goa College of Pharmacy, Panaji-Goa.

Near infrared (NIR) spectroscopy is a specialized branch of spectroscopy and shares many attributes of other spectroscopic methods. The NIR spectral region is defined as a band of wavelength from 0.1 to 2.3 micrometres. This technique is fast, simple, accurate, non destructive and can be performed on the product in its normal state. These points make NIR spectroscopy highly suitable for production control and enable more frequent sampling checks than with any other analytical method.

Present work describes quantitative estimate of ciprofloxacin HCl 250 mg tablets by taking five different strengths of nominal concentration ranging from 80% to 140%. Tablets were prepared by varying the concentration of drug vis-à-vis excipients. 20 samples out of each range of nominal active content were measured with NIR spectrophotometer (NIRTAB). To improve S/N ratio the reflectance spectra were taken using 10 scan accumulations. A standard validated HPLC method was used to provide the reference analysis of active content. For chemometric analysis, partial least square method was applied.

To determine the specificity placebo tablets were prepared and analyzed as per the proposed method. The excipients showed no interference with the spectra of ciprofloxacin HCl. The method was found to be accurate and precise as the results obtained were comparable to reference HPLC method (RSD=0.82). The other parameters like repeatability, intermediate precision, linearity and robustness were evaluated and the validated study is supported with a complete set of statistical data.

GP$_3$ Simultaneous estimation of nicotinic acid and simvastatin by packed column supercritical fluid chromatography (pcSFC)

K. M. Patil*, N. R. Lad, K. K. Nerurkar and I. C. Bhoir

Shri C B Patel Research Centre for Chemistry & Biological Sciences, IIIrd Floor, Bhaidas Hall Building, Vile-Parle (W), Mumbai 400 056

An isocratic, simultaneous method based on pcSFC separation and estimation of two a lipid regulating drugs viz. nicotinic acid and simvastatin. The analytes were separated by elution with supercritical fluid carbon-dioxide doped with 9.09 % methanol [containing 0.5 % acetic acid (v/v)] on m Bondapak phenyl (300 X 3.9 mm i.d., 10 mm) column. The primary modifier methanol was unable to separate two drugs, so 0.5 % acetic acid was used as secondary modifier for separation. The eluted analytes were monitored spectrophotometrically at 230 nm. The densities and polarities of the mobile phase were optimized from the effect of pressure, temperature and concentration of modifier on chromatographic figures like retention time ($t_{R\ min}$), capacity factor (k'), selectivity (a), resolution (R), asymmetry (T) etc. Modifier concentration proved to be the most effective means for changing both retention and selectivity. Calibration,

accuracy, precision and recovery of the method were determined in order to validate the method. From perusal of this large data a selection of best chromatographic conditions leads to a value of 11.77 MPa pressure, 35°c temperature, 9.09 % (v/v) modifier concentration doped with 2.0 ml/min flow rate of CO_2. The total run time was about 10.0 min. The recoveries were 100.08 % and 99.62 % for nicotinic acid and simvastatin respectively. The quantitation was carried out using cilostazol as the internal standard. The present work suggests new novel method for the simultaneous assay of nicotinic acid and simvastatin using supercritical fluid carbon-dioxide and modifiers alternative to RP-HPLC.

Isocratic pcSFC, Nicotinic acid and Simvastatin.

GP$_4$ Bioanalytical method development and validation for atorvastatin

Sudhakarr.B*,Sivakumar.S.P.N,Shankari.P, Vasudevan.M, Ravisa Nagarajan J.S.K and Suresh B.

J.S.S. College of pharmacy, Ootacamund, The Nilgiris

A reversed phase chromatographic method for the estimation of Atorvastatin has been developed and validated. Blank plasma samples collected from volunteers were centrifuged at 3000 rpm to separate the plasma. It was then spiked with a known quantity of the drug and internal standard. The spiked samples were deprotenised using acetonitrile and centrifuged. The supernatant was collected and analysed for the drug content. Shimadzu system with Hypersil phenomenox® C_{18} (5m, 25cm x 4.6mm i.d) column was used for the analysis. A mixture of acetonitrile and 0.5%triethanolamine buffer of pH 3.5 in the proportion 50:50v/v was used as the mobile phase at a flow rate of 1ml/min and an operating pressure of 3000 psi. Samples equivalent to 100 µl were injected through Rheodyne injector. Pioglitazone was used as internal standard and the detection was done at 250 nm using a Photo Diode Array (PDA) detector. The method was further validated for its accuracy, precision, sensitivity, selectivity, linearity and range. It was concluded that the developed method for the estimation of Atorvastatin may be applicable for the routine blood level estimation, especially in bioavailability, bioequivalence and therapeutic drug monitoring studies.

GP$_5$ Stability indicating HPTLC determination of meloxicam as bulk drug and in pharmaceutical preparations

Shah S. P.*, Rajadhyaksha N. S. and Amin P. D.

D/202, Shankar Lane, Kamal Appt., Kandivli (W), Mumbai 400 067

Meloxicam is a new NSAID of the oxicam class, developed for the treatment of Rheumatoid and Osteoarthritis, which differs from other NSAIDS in that it is a selective COX - 2 inhibitor. A High Performance Thin Layer Chromatographic method of analysis was developed for Meloxicam and the drug in formulation. The mobile phase selected was Ethyl acetate: Cyclohexane: Glacial acetic acid (6.5:3.5:0.02 % v/v/v). The calibration curve of the drug was linear in the range of 100 - 400 ng. The spectrodensitometric analysis was carried out at 353 nm. The mean (+ RSD) values of slope, correlation coefficient and intercept were 3275.6 ± 0.358, 0.9980 ± 0.0321 and 14442.667 ± 7.1 respectively. The system precision and the method precision studies were carried out with an RSD of 3.3 % and 0.83 % respectively. The limit of quantitation and detection were 30 ng and 99 ng respectively. The mean percent recovery was found to be 100.3%. Meloxicam was degraded by exposing the drug to base degradation and oxidative degradation. The degraded products were well separated from the pure drug with significantly different R_f values suggesting a stability indicating analysis method for the quantification of Meloxicam in pharmaceutical preparations and as bulk drug. The method was used to analyze Meloxicam from marketed tablet formulation. The reported method is simple, selective, precise, accurate, time saving and economic.

GP$_6$ Serum level estimation of phenobarbitone by solid phase extraction and spectophotometry

Presannakumaran.P.N*, Haripriya M, Helen William C.Renjish

Barbiturates are widely used drugs for the treatment of epileptic seizures. Their therapeutic window is narrow and large individual variations exist in the serum level. Hence it is an important drug requiring therapeutic drug monitoring. Phenobarbitone is a commonly encountered drug in many suicide cases. In such poisoned patients a serum level estimation of the drug is required to say whether a dialysis is required or not. Literature survey has revealed that numerous techniques like GC,GC-MS,HPLC and polarization and fluoroimmunoassay etc. are available, which require sophisticated equipments. So the objective of the work was to develop a simple, cost-effective and an easy method for the estimation of phenobarbitone in serum samples. Thus a new method called solid phase extraction was employed in this estimation. Solid phase extraction (SPE) is a method that uses a solid phase and a liquid phase to isolate one or one type of analyte from a solution.

SPE column (Drug test 1,130 mg) was used in the extraction of phenobarbitone from serum. The sample was prepared by adding 2ml of 0.1M phosphate buffer(pH 6) to 1ml of serum. It was applied to previously conditioned column. The column was successively rinsed with 1ml of 0.1 M of Phosphate buffer : Methanol(8:2), 1ml of 1M Acetic acid and

finally with 1 ml of hexane. The drug was eluted from the column using 4ml of dichloromethane under gravity flow. The solvent was evaporated off, the residue was dissolved in 2ml of 0.5M NaOH and the absorbance was measured at 254nm.

A standard curve was constructed with concentration on the X-axis and absorbance on the Y-axis, by taking 20,40,60,80 mg of phenobarbitone sodium in 1 ml of normal serum and performing solid phase extraction as explained above. The unknown serum level concentration of the patient was obtained from the graph against its absorbance.

GP$_7$ A simple, rapid, sensitive HPLC method for the estimation of nicotine in plasma

G. Subramanian, Shaila Lewis, S. Pandey and N. Udupa*

College of Pharmaceutical Sciences, MAHE, Manipal 576 119

A simple, rapid and sensitive high performance liquid chromatographic method was developed for the analysis of nicotine in plasma. This method involved simple extraction procedure prior to chromatographic analysis. The chromatographic separation was achieved on a reverse phase C_{18} column with ultra violet detection at 260 nm. The mobile phase consisted of 0.3% Triethylamine. Buffer adjusted to pH 7.0 using phosphoric acid and Methanol in the ratio of 60:40. The isocratic system was operated at ambient temperature and require 20 min of chromatographic time at a flow rate of 1 mL/min. Acetanilide was used as an internal standard. The extraction method of nicotine from plasma is very simple and the recovery was found to be 85%. The interday precision was found to be 7.6%. The method was validated and it can be used in the pharmacokinetic studies of nicotine preparations.

GP$_8$ An explanation for the physical instability of the marketed formulation of isoniazid and ethambutol

Hemant Bhutani*, T.T. Mariappan and Saranjit Singh

Department of Pharmaceutical Analysis, NIPER, Sector 67, S.A.S. Nagar, Punjab 160 062

One of the marketed strip packed anti-tuberculosis formulation containing isoniazid and ethambutol from a leading Indian company was found to have a fine sheet of white powder inside the strip pockets. The product was just 4 months old at the time of purchase, of the total labelled shelf life of 5 years. The present study was done to explore the possible reasons for the physical instability typical to this formulation.

The investigation was focussed both on the packaging material and the formulation. Scanning electron microscopy studies provided evidence of the presence of pinholes in the strip package. This indicated that moisture could ingress through the package from these pinholes and it was the cause of subsequent instability of the formulation. To understand this formulation related instability, moisture gain studies were carried out on pure H and E and their physical mixtures, varying the ratio of the two drugs from 10:90 to 90:10 w/w. The studies were carried out in open beakers at accelerated conditions of temperature and humidity (40 °C and 75% RH) in a stability chamber. Samples containing E > 60 %w/w in mixtures of H:E gained sufficient moisture to become liquid. When these samples were taken out of the chamber, the solutions crystallized, with the time of crystallization varying with different compositions of H:E. Also, the nature of crystals was investigated microscopically. In addition, FT-IR studies were done to see if any chemical change occurred during storage of H:E mixtures in the stability chamber.

On withdrawal of samples out of the chamber, the mixture containing H:E, in a ratio of 30:70 w/w, got crystallised from the solution instantaneously, while others took longer period. Crystallization of pure ethambutol took maximum time, around 10 h. Incidentally, this ratio was the same as that of the marketed formulation (28:72 w/w). An inference drawn here is that the combination of H and E in a ratio of 30:70 w/w is a critical composition that results in a saturated solution subsequent to dissolution of both H and E in the gained moisture. In solutions containing higher content of E, the H quantity is not enough to yield a saturated system, and in situations where H is more than 30%, the E strength is low and hence the available moisture is not enough to yield a complete soluble system for both the drugs.

Microscopic studies revealed that pure E (0:100 w/w) crystallised out as fine plates, but the inclusion of H resulted in distortion of these plates. There was sudden deformation of crystal structure at 30:70 w/w ratio of H:E. FT-IR spectra showed that there was no chemical interaction between the two drugs.

It is hence postulated that the fine layer of powder seen inside the marketed strips occurs due to dissolution of drugs in the gained moisture and their subsequent crystallization when the formulation is exposed to dry conditions during distribution.

GP$_9$ Development of forced degradation profile of rosiglitazone using HPLC

S.P.N.Sivakumar*, Sudhakarr.B, VenkatRoa.J, Vasudevan.M, J.S.K.Nagarajan and B.Suresh

Dept of Pharmaceutical Analysis, J.S.S. College of Pharmacy, Ooty

Rosiglitazone (RG) chemically ± 5-(p-[2-(methyl-2-pyridyl amino) ethoxy] benzyl)-2, 4-thiazolidinedione is an antidiabetic.Stability Indicating HPLC methods

are required in carrying out stability studies of drug substances. Moreover they provide data on forced degradation products & decomposition mechanism for the drugs. The present paper describes the forced degradation studies that were carried out to investigate the intrinsic stability of the Rosiglitazone using LC. Acid hydrolysis, alkali hydrolysis, neutral hydrolysis, chemical oxidation were carried out using standardized protocols & the degradation products were analysed by developed HPLC methods. The methods were then validated as per ICH guidelines. A shimadzu system with symmetry® Phenomenex Luna C_{18} column,(25 cm x 4.6mm i.d.,5m)was used for the analysis. A mixture of acetonitrile & 25mM Phosphate buffer (pH 3.5) in the proportion 75:25 v/v was used as a mobile phase at a flow rate 1.0 ml per minute. Sample equivalent to 100ml were injected through Rheodyne injector & the detection was done at 320 nm with Photo Diode Array (PDA) multiwavelength detector. The results of the above studies revealed that there was no degradation by stress condition, indicating that the drug is practically stable under the conditions tested.

GP$_{10}$ RP-HPLC method development and validation of oxybutynin hydrochloride extended release tablets and Buccaltablets in human plasa

Rajesh.M*, Praveen.K, Senthamil selvan.P, Vasudevan.M, J.S.K.nagarajan, and Suresh. B

Department of pharmaceutical Analysis, J.S.S. College of pharmacy, Ootacamund.

A reversed phase chromatographic method for the estimation of Oxybutynin Hydrochloride extended release Tablets and Buccal Tablets has been developed and validated. Blank plasma samples collected from volunteers were centrifuged at 3000 rpm to separate the plasma. It was then spiked with a known quantity of the drug and internal standard. The spiked samples were deprotenised and extracted. The extract was collected and analyzed for the drug content. Shimadzu® LC-10AT HPLC system with Phenomenex LUNA® C_{18} (5m, 25cm x 4.6mm i.d) column used was for the analysis. A mixture of acetonitrile and 0.5%Triethylamine of pH 3.5 in the proportion 40:60 v/v was used as the mobile phase at a flow rate of 1ml/min and an operating pressure of 3000 psi. Samples equivalent to 100 µl were injected through Rheodyne 7725i injector. Diphenylpyraline was used as internal standard and the detection was done at 200 nm using SPD-M 10A VP Photo Diode Array (PDA) detector. The method was further validated for its accuracy, precision, sensitivity, selectivity, linearity and range. It was concluded that the developed method for the estimation of Oxybutynin Hydrochloride extended release Tablets and Buccal Tablets may be applicable for the routine blood level estimation, especially in bioavailability, bioequivalence and therapeutic drug monitoring studies.

GP$_{11}$ RP-HPLC method development and in vitro evaluation of marketed Ciprofloxacin hydrochloride tablets

D.M. Patel, N. M. Patel, R. R. Shah, P. D. Jogani and N. R. Patel

B.M. Shah College of Pharmaceutical Education and Research, College Campus, Modasa (Gujarat) 383 315

A simple, specific, accurate, sand precise reverse phase high performance liquid chromatographic method was developed for estimation of ciprofloxacin hydrochloride in its tablet dosage forms. A Lichrospher^{a} 100 C-18, 5 mm column having 20 x 4.6 mm i.d. in isocratic mode, with mobile phase containing 20 mM KH_2PO_4 buffer (pH adjusted to 3.00 ± 0.1 with 10 % v/v phosphoric acid): acetonitrile: tetrahydrofuran in 600:300:100 were used. The flow rate was 1.0 ml/min and effluent was monitored at 272 nm. The retention time was 2.26 min. The reported spectrophotometric method was also used for linearity and analysis of ciprofloxacin hydrochloride in tablets. The linearity for ciprofloxacin hydrochloride by RP-HPLC method and spectrophotometric method was in the range of 1-10 mg/ml with co-efficient of correlation (r) 0.9999 and 0.9997 respectively. Average % recovery obtained for ciprofloxacin hydrochloride was 99.26 %. In replicate analysis n=3 of ciprofloxacin hydrochloride in tablet dosage forms by proposed method and by spectrophotometric method, the average content of ciprofloxacin hydrochloride found were 505.42 mg/tablet (RSD=1.491 %) and 502.5 mg/tablet (RSD=1.385 %) respectively. Limit of detection (LOD) and limit of quantification (LOQ) by proposed RP-HPLC method were found to be 0.05mg/ml and 1mg/ml for ciprofloxacin hydrochloride respectively. Tablets were also evaluated for in vitro evaluation parameters like hardness, thickness, friability, content uniformity, weight variation test, disintegration and in vitro dissolution test.

GP$_{12}$ Estimation of cefdinir in formulation by spectrofluorimetric method

A. Suganthi*, Sapna Shrikumar, Minu B. Pattesseril, M. Uma Mageshwari, T. K. Ravi

College of Pharmacy, SRIPMS, Coimbatore 641 044

Cefdinir is an extended spectrum, semisynthetic cephalosporin antibiotic for oral administration. It is chemically designated as (6R-[6a, 7b (z)]-7-{[2-aminothiazolyl (hydroxyiminoacetyl) amino]-3-ethenyl-8-oxo-5-thia-1 azabiacyclo [4.2.0] Oct-2ene-2-carboxylic acid. Empirical formula of cefdinir is $C_{14}H_{13}N_5O_5S_2$ and its molecular weight is 395.42.

From literature review it was found out that there is no official method of analysis described in IP, BP and USP for the estimation of cefdinir. An extensive literature survey on the drug indicates that the reported method of analysis include only HPLC method for the estimation of cefdinir from biological fluids. As no single analytical method is reported for the estimation of cefdinir from formulation, the present work aims at reporting a simple and specified method of analysis of cefdinir from its capsule formulation.

An accurate and sensitive fluorimetric method for the estimation of cefdinir has been established using Jasco model FP/750 fluorimeter. pH 7 phosphate buffer was the solvent of choice for the drug. The selected excitation and emission wavelengths were 262nm and 530nm with a bandwidth of 5nm for the proposed study. The substance showed the linearity range between 0.2 to 1 mg/ml by plotting concentration vs. fluorescence intensity using 9ml of 1M sodium hydroxide at 95°C for 1 hour. The quantum efficiency on fluorescence characteristics of the drug was found to be 0.9767 using quinine sulphate as reference. In this method, the fluorescence intensity was stable for 2 hours. The percentage recovery studies indicated that there was no interference from diluents and lubricants.

GP 13 Study of polymorphism in raw materials and formulations of sertraline hydrochloride

Badiger.A.M[a]., D.Satyanarayana [a], Nayak.V.P [b]., Joshi.S.D., Veerapur.V.P. and Shastry.C.S.

[a] SET College of Pharmacy, Dharwad

a. NGSM, Institute of Pharmacy, Mangalore. b Kuvempu University, Shimoga

A polymorph is solid crystalline phase of a given compound resulting from possibility of at least two different arrangements of molecules of that compound in the solid state. Two polymorphs will be different in crystal structure but identical in the liquid and vapor states. Polymorphic variations in compounds are reported to affect the thermodynamic stability of the compound. The physical and chemical properties that vary within different polymorphic forms of a compound will lead to marked difference in the blood concentration of drug.

The implications of polymorphs in formulation and development of a dosage form is a well-known phenomenon. The different polymorphic forms of drug might have different physical as well as chemical properties and the same are reflected in the formulation process like, phase conversion of a polymorph in suspensions leading to problems like crystal growth and caking. Phase inversion due to the use of a wrong polymorph in creams leading to crystal growth. Further, use of a wrong polymorph might lead to difference in solubility of solution leading to deviation from the fixed concentration of the solutions. In essence the polymorphic form of a compound may have major effect on bioavailability of a drug and its shelf life. In view of this the present study orients at studying the polymorphic forms of the antidepressant drug Sertraline Hydrochloride using various instrumentation techniques like Infrared spectroscopy, Differential scanning calorimetry and X-ray diffraction studies.

Sertraline Hydrochloride a serotinin reuptake inhibitor exists in 5 polymorphic forms. The study was carried out to evaluate the polymorphic form of the drug being marketed. Different marketed formulations and raw materials were subjected to instrumental techniques to study the polymorphic form present in them. The formulations with excepients were subjected to FT-IR spectroscopy. Interference of excepients in XRD and DSC was overcome by isolating the compound from various solid dosage forms. The FT-IR spectrum of different polymorphic forms gave distinct frequency patterns. X-ray powder diffraction studies revealed the presence of polymorphic form-I in the dosage forms and the same was supported by the results obtained from differential scanning calorimetry. The Results indicate that out of 4 formulations taken for study, three of the formulations were having thermodynamically stable polymorph. Further, no marked change in stability of the solid dosage form was observed on subjecting to elevated storage conditions. The study needs further pharmacokinetic investigations of different polymorphic forms of the drug to find out the difference in blood concentration of the drug at biophase and hence a difference in the therapeutic value.

GP 14 Simultaneous spectrophotometric estimation of tizanidine and Ibuprofen in their dosage forms

***G.Nagaraja Perumal, P.Lingeshwara Rao, A.Siyad, S.N.Meyyanathan and B.Suresh.**

J.S.S. College of Pharmacy, Rocklands, PB. NO : 20, Ootacamund - 643 001, (T.N.)

Tizanidine is a skeletal muscle relaxant and Ibuprofen is a non-steroidal analgesic and anti-inflammatory agent. A combination of 2mg of tizanidine and 400mg of ibuprofen is commercially available as tablets. Literature survey reveals that no analytical method is available for its estimation in their dosage forms. A simple, rapid and reproducible method was developed for the concurrent estimation of tizanidine and ibuprofen in their dosage forms .The λ_{max} for tizanidine and ibuprofen were found to be 306.4nm and 222.0nm respectively. Beer's law was obeyed in

the concentration range of 0-50mg/ml for tizanidine and 0-10 mg/ml for ibuprofen. The sample solution is prepared within the calibration range containing both tizanidine and ibuprofen was kept in the sample cell of the double beam spectrophotometer and the absorbance was recorded at 306.4 nm, keeping the standard solution of ibuprofen of equivalent strength in reference cell. The absorbance values were fed to standard curve of tizanidine and get the concentration of tizanidine in the sample. Similarly the absorbance was recorded at 222.0 nm, keeping the standard solution of tizanidine of equivalent strength in the reference cell to obtain the concentration of ibuprofen in the sample. The reliability and efficacy of the proposed method was confirmed by the recovery studies, statistical evaluation and then method was applied successfully for the estimation of pure drug as well as in pharmaceutical dosage forms.

GP 15 Bioanalytical method development and validation for rofecoxib using frusemide as a internal standard

Praveen.K*, Rajesh.M, Swapna.M, vasudevan.M, Nagarajan J.S.K, Suresh.B

J.S.S. College of pharmacy, Ootacamund, (TN)

Rofecoxib is chemically 3-phenyl 4[4'methyl Sulfurdioxo]-2-oxo-dihydrofuran.Rofecoxib is a non steroidal anti-inflammatory drug that exhibits anti-inflammatory, analgesic and antipyretic activities in animal models. The mechanism of action is believed to be due to inhibition of prostaglandin synthesis, via inhibition of cyclooxygenase-2(COX-2).At therapeutic concentrations in humans, Rofecoxib does not inhibit the cyclooxygenase-1(cox-1) isoenzyme.

The present work describes a reversed phase HPLC method for estimation of Rofecoxib. The validation of the proposed method was also carried out. A Shimadzu® HPLC system was used for the analysis. The method was carried out Stationary phase on YMC pack ODS (25cm´ 4.6cm i.d, 5µ, S.NO-(042553167) column with a Mobile phase consisting of Acetonitrile: 0.5%of Triethylamine (pH adjusted to 3.5 with ortho phosphoric acid) (45:55 v/v) at a µinjector with a 20 ml loop was used for the injection of samples. The SPD-M10 Avp Diode array detector was used to detect the drug at 280 nm and CLASS VP data station was used to process the Chromatograms. The mobile phase was filtered through a 0.2m membrane filter and degassed. The separation was carried out at room temperature of about 20±2 °C.

GP 16 Simultaneous estimation of metformin hydrochloride and pioglitazone in combined dosage forms by RP-HPLC

Wanjari D. B.* and Gaikwad N. J.

University Department of Pharmaceutical Sciences, Nagpur (M. S.) 440 033

A simple, precise and rapid reverse phase high performance liquid chromatography method has been developed and validated for the estimation of Metformin Hydrochloride and Pioglitazone in combined dosage form. The separation was achieved by using phenyl bonded (250 x 4.6 mm) column and mobile phase consisting of water : methanol : acetonitrile : triethylamine (620:170:210:1 v/v), pH adjusted to 3.0 with orthophosphoric acid, at a flow rate of 1.0 ml/min. Detection was carried out at 215 nm. The dilutions of standard and sample were made in mobile phase. The retention times for Metformin Hydrochloride and Pioglitazone were found to be 3.5 and 7.7 min. respectively.

The further validation of this method, recovery studies were carried out by adding a known amount of the drug to the test solution and the percentage recoveries were found between 99-101% for both the drugs. The linearity of Metformin Hydrochloride and Pioglitazone were in the range of 50-200 µg/ml and 1.5-12 µg/ml respectively.

The method was successfully applied for the determination of cited drugs in its tablet dosage form with good accuracy and precision. The results were also confirmed statistically.

GP 17 Simultaneous spectrophotometric estimation of cefadroxil and ambroxol in combined dosage form

Esther Roset Shobana* and Lakshmi Sivasubramanian**

Department of Chemistry, (Pharmaceutical Chemistry) Vellore Institute of Technology, Vellore - 632 014.

Cefadroxil is a phenolic beta lactum antibiotic and is Official in IP 1996. Ambroxol is a mucolytic drug and is official in Martin Dale - Extra pharmacopoeia - 1996. Combination of Cefadroxil and Ambroxol is used for the treatment of respiratory tract infections. However, literature survey revealed that no analytical method has been reported for this combination.

A simple, precise and economic spectrophotometric method has been developed for

the simultaneous determination of both in bulk and in formulation.

Multicomponent mode of Shimadzu UV - 1601 was used to perform analysis using methanol as a solvent. Five mixed standards were employed in the multicomponent mode using two sampling wavelengths as 230 nm and 245 nm.

The reliability and efficacy of the proposed method was confirmed by recovery studies and statistical calculations. The method was free from interference by formulation excipients as well as from mutual interference of the two drugs. Also this method is simpler than the other spectrophotometric method.

GP 18 Estimation of ondansetron by reverse phase high performance liquid chromatography

R. Bino Kingsley*, R.Ravi, S. Sathesh Kumar , T.N.K. Surya prakash, J.Anbu Jeba Sunilson

Department of Pharmaceutical Chemistry, S.B. College of Pharmacy, Sivakasi - 626 130.

Odansetron is chemically (±) 1,2,3,9 -tetra hydro-9-methyl 3 ((2-methyl-IH-Imidazole-1-yl) methyl] -4H-Carbazol-4-one.The tablet contains 4 mg of ondanserton which is mainly used for nausea and vomiting that occurs with many form of cancer Chemotherapy.

Literature survey reveals that there is no method for the estimation of this drug by H.P.L.C, hence the present work describes a reverse phase H.P.L.C method for the estimation of this drug.

A simple precise fast and selective R.P.H.P.L.C method was developed for the estimation of ondansetron in its dosage form.Column used wasC_{18} (4.6mm x 250id) in isocratic mode with mobile phase disodium hydrogen ortho phosphate and acetonitrile (50:50) and pH was adjusted to 2.53 with ortho phosphoric acid at a flow rate of 1ml / min and the wave length was detected at 210nm. The retention time of ondansetron was 3.080 min respectively. The amount taken for assay is 40 µg /ml of odansetron and the amount found was 40.46 mg/tab. The percentage label claim obtained for odansetron is 100.52%. Hence the proposed method is accurate, precise rapid for the estimation of odansetron.

GP 19 Development and validation of gas chromatographic method for the determination of self generating alcohol in abhayarishta

Sailesh J. Wadher*, P.G.Yeole, Chandrakant Lokhande

Institute of Pharmaceutical Education and Research, Wardha

A simple sophisticated and reproducible Gas chromatographic method for determination of self generating alcohol in Abhayarishta was developed and compared with specific gravity method [1,5],a traditional method for alcohol determination. The Gas chromatographic method involve use of carbowax 20m stationary phase .

The comparison of Gas chromatography[2] and specific gravity method was carried out by using t-test. T-test shows that Gas chromatographic method was better by level of significance of 0.05($p<0.05$)

Gas chromatography is widely used technique for separation of gaseous and volatile substances which are difficult to separate and analyze. It is rather simple and inexpensive method, generally efficient in regard to separation. The instrumental method has advantage over classical method because they are more accurate, precise ,sensitive ,selective and less time consuming .Review of the literature indicate that the Gas chromatography method is routinely adopted for determination of ethanol in urine and serum, probably because it is comparatively simple ,sensitive, and speedy.[4]

We have developed a Gas chromatographic method, for quantitative estimation of self generating alcohol in Abhayarista, and compared with specific gravity method.

The samples of Abhayarishta from Baidhyanath, Dabar, Sandu,Unza were collected from the market. Gas chromatographic system consisting of a carbowax 20m stationary phase was used.

GP 20 Bioanalytical method development of pantoprazole tablets

Sajjad.S*, Kulkarni Sumant S., Venktesh.G, M. Vasudevan, J.S.K. Nagarajan and B. Suresh.

J.S.S. College of Pharmacy, Ootacamund 643 001 (TN)

Pantoprazole is chemically 5-(difluoromethoxy)-2-{[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl}-1H-benzimidazole sesquihydrate sodium.Pantoprazole is a proton pump inhibitor (ppi)that suppresses the final

step in gastric acid production by forming a covalent bond to two sites of the(H+,K+)ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect is dose related and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding of the (H+,K+) ATPase results in a duration of anti-secretory effect that persists longer than 24 hours.

The present work describes a reversed phase HPLC method for estimation of Pantoprazole.. A Shimadzu® HPLC system was used for the analysis. The method was carried out Stationary phase on Phenomenex Luna column(C18,25cm´4.6mm i.d,5m)with a mobile phase of Triethyl amine solution(pH 7.0) and acetonitrile solution with a solvent ratio 65:35%v/v at a m injector of 20µl loop.. The SPD-M10 Avp Diode array detector was used to detect the drug at289nm.CLASS VP data station was used to process the Chromatograms. The mobile phase was filtered through a 0.2m membrane filter and degassed. The separation was carried out at room temperature of about 20±2 ^{0}C.

GP$_{21}$ Resolution and characterization of stereoisomeric quininone oximes by microcalorimetric studies

V.K. Kapoor*, Renu Chadha, Kamal Kumar and Amit Kumar*

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh-160014. India.

Two stereoisomers of quininone oxime have been resolved and characterized using the technique of microcalorimetry. It is a fast emerging technique, which is finding extensive use in modern drug discoveries, as it is a non-invasive, non-destructive and independent of sample form. The technique has been successfully utilized for crystallinity determination and characterization of pharmaceuticals. The quininone oximes could be resolved through painstaking technique of column and preparative thin-layer chromatography, into its two isomeric forms with different melting points. The calorimetric study was carried out using a high sensitivity heat flux microcalorimeter model C-80 (SETARAM, France), which allows measurement of rate of heat produced from sample with a sensitivity of about 10^4 times greater than what is measured by DSC.

The appropriate configuration was assigned to them depending on the results obtained by measuring heats of solution in ethanol and chloroform, microcalorimetrically. The proposed geometries were further supported by the heats of solution in aqueous solutions over the pH range from 1-9. Heat of solution was found to be exothermic for minor oxime and endothermic for major oxime in chloroform. However both the stereoisomers showed endothermic behaviour in ethanol, although the absolute value was less in case of minor oxime. The heat of solution also increased with increase in pH for both the isomers. The major oxime was assigned anti configuration whereas minor oxime was assigned syn configuration based on above observations.

The results were further supplemented by FTIR. In IR spectra, shift in bendings of major oxime at 1261.5 cm^{-1}, 934.5 cm^{-1} and 3152.7 cm^{-1} to 1254.2 cm^{-1}, 914.2 cm^{-1} and 3167.7 cm^{-1} in minor oxime, respectively.

GP$_{22}$ Development and validation of RP-HPLC method for determination of Cefixime trihydrate in pharmaceutical dosage forms

K.E.V. Nagoji*, J.V.L.N. Seshagiri Rao, K. Venugopal**, M.E.B. Rao***

*Pharmaceutical Analysis and quality control division, Roland Institute of Pharmaceutical Sciences, Berhampur (Gm) - 760 010, Orissa.

** Pharmaceutical Analysis and quality assurance division, Andhra University, Visakhapatnam.

Cefixime is orally active cephalosporin which is effective against strains of E.Coli, K. Pneumonia, Enterobacter, Citrobacter, Salmonella, Shigella, Proteus that are resistant to first and second generation cephalosporins. It is useful in the treatment of bronchitis, gonorrhea, urinary tract infections, pharyngitis, influenza and tonsillitis. Cefixime is not official in any pharmacopoeia. A simple, selective, rapid, precise and economical reverse phase HPLC method has been developed for the determination of cefixime in pharmaceutical dosage form. Nevirapine was used as an internal standard (IS). A HPLC system consisting of isocratic pump, reverse phase C-18 analytical column and UV-Visible detector set at 230nm was used. The mobile phase composed of methanol and water in the ratio of 50:50 (v/v) was pumped at a flow rate of 0.9 ml/min. The drug and IS were eluted at 2.05 and 6.7 min respectively. The method was validated for its linearity, precision and accuracy. The calibration curve was linear in the range of 0.05 to 90 mg/ml. The intra and inter-day variation was found to be less than 1.52% showing high precision of the assay method. The mean recovery of the drug from the solutions containing 2, 4 and 10 mg/ml was 99.0-102.9% indicating high accuracy of the proposed HPLC method.

GP 23 Standardization of some ayurvedic bhasmas

Dr. P.G. Yeole, R.O. Ganjiwale, R. P. Kalsait,* P.P. Aparajit

Institute of Pharmaceutical Education and Research, Borgaon (Meghe), Wardha 442 001, MS

Bhasma's played an important role in ayurvedic system of medicine. These are powder substances obtained by calcination. Bhasmas are applied to metals , minerals and animal products , which are by special process, Calcinated in closed crucibles in pits and with cow, dung cakes (puts) Bhasmas are prepared by 1) Sodhana. & 2) Marana

Sodhana has two steps Samanya Sodana and Vishesha Sodhana. Vishesha Sodhana consist of Bhavana, Svenada, Nirapana, mardhana,

Copper & Iron are the ingredients of Bhasmas, their ayurvedic preparation are Loha bhasma, Tamra bhasma , svarnamakshika bhasma. Method for determination of copper & iron are as follows

1)Gravimetric method. 2) Titrimetric method. 3) colorimetric method. 4)Atomic absorption spectroscopy. 5) Inductive coupled plasma analysis. 6)X-ray fluoroscence.

Other test for standardization are solubility, fineness of particle, Bulk density, Loss on dring, Loss of ignition, Acid insoluble ash are performed.

GP 24 Estimation of tizanidine, diclofenac and paracetamol in multi-component dosage form by RP-HPLC method

Prashant M and Subramanian.G*

Department of Quality Assurance, College of Pharmaceutical Sciences, Manipal 576104

Tizanidine HCl is 5- Chloro-4-[2imidazolin 2 yl amino]2, 1, 3 benzothiadiazole used as skeletal muscle relaxant. Diclofenac potassium is used as non-steroidal anti-inflammatory drug and it is chemically potassium [o- (2,6-dichloroanilino)phenyl] acetate. Paracetamol, chemically 4- hydroxy acetanilide, is a centrally and peripherally acting non-opioid analgesic and antipyretic The marketed tablet contains 2 mg of tizanidine, 50 mg of diclofenac potassium and 325 mg of paracetamol as labeled claim. This combination is used for spasm and pain associated with musculoskeletal disorders. A literature survey revealed that there are number of methods have been reported for the estimation of Diclofenac and Paracetamol, individually or in combination with other drugs however, there is no method reported for the simultaneous estimation of these drugs. Hence the present work describes a reversed phase HPLC method for simultaneous estimation of these two drugs in tablets. The validation of the proposed method was also carried out. A Shimadzu HPLC system was used for the analysis. The method was carried out on a Luna C_{18}, (25 cm x 4.6 mm i.d., 5m) column with a mobile phase consisting of acetonitrile: phosphate buffer (pH adjusted to 7.0 using orthophosphric acid) (40:60%v/v) at a flow of 1.0 ml min-1. Detection was carried out at 220nm. Carbamazepine was used as internal standard. The validation of the method was also carried out. The separation was carried out at the room temperature of about 20°C ± 1. Detection was carried out accuracy, precision, LOD, LOQ, ruggedness and robustness according to ICH /USP guidelines. This demonstrates that the HPLC methods developed is rugged and robusted. The proposed methods can be used for simultaneous estimation.

GP 25 Separation and estimation of zafirlukast and its impurity using high performance liquid chromatography

Nilesh R. Lad*, K.K. Nerurkar, K.M. Patil, I. Bhoir and A. M. Bhagwat

Shri C B Patel Research Centre for Chemistry & Biological Sciences, IIIrd Floor, Bhaidas Hall Building, Vile-Parle (W), Mumbai 400 056

Zafirlukast an antihistamine drug and its impurity viz, o-Toluene sulphonamide have been determined using a HPLC method. The elution was performed on Nucleosil C_{18} (250 x 4.6mm) 5mm column, using mixture of 50mM KH_2PO_4, methanol and acetonitrile in the proportion of 40:10:50 (v/v/v) as the mobile phase at the flow rate of 1.0 ml/min. The analytes peaks were well resolved and separation achieved in 10 min. Detection was carried out using UV spectrophotometer set at 254 nm. The data was evaluated by the linear regression least squares fit method, linearity ranges of 6.0 to 50 mg/ml for impurity and 0.6 to 5.0 mg/ml for Zafirlukast. The correlation coefficient were >0.999 for both the analytes. The method was successfully employed to estimate levels of 0.1 - 0.2 % of the impurity with respect to Zafirlukast.

GP 26 Determination of mycophenolic acid in human plasma by RP-HPLC with UV detection

C.A. Trivedi*, K. Soni, P. Suresh Kumar, I.J. Khan, R.S. Mandke, A.C. Walekar and M.N. Saraf

The Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai-400 098.

A simple, fast and sensitive high-performance liquid chromatographic method for the determination of mycophenolic acid in human plasma has been developed. The chromatographic system uses a C-18 column with UV detection at 251 nm. Mobile phase consisted of 0.1M Phosphate buffer (pH 3.2 ± 0.1) : Acetonitrile in the ratio of 45:55 at a flow rate of 0.8 mL/min. Mycophenolic acid was extracted by simple protein precipitation with acetonitrile. The overall mean extraction recoveries were above 85%. The calibration curve was linear in the concentration range of 10 ng/ml - 10 µg/mL. This simple and sensitive method allows for the determination of the range of plasma concentrations that is observed after administration of clinically relevant doses of mycophenolate mofetil.

GP$_{27}$ Determination of organic volatile impurities in oral solid coated dosage forms

Balaphanisekhar. A. *, Dr. Sanjay Pai P.N. and Dr. Gopalkrishna Rao

Department of Quality Assurance, Al-Ameen College of Pharmacy, Bangalore 560 027

Organic solvents are entrapped within the formulation either during the course of manufacture of active pharmaceutical ingredients or during the coating of the formulation. These solvents are used frequently to dissolve film-coating materials like methyl cellulose, ethyl cellulose etc to facilitate application onto compressed tablets. These tablets are subjected to air-drying to remove all the organic solvents from the coat of finished product. In the present work a method for simultaneous identification and quantification of some common residual solvents by using direct injection capillary gas chromatograph with a flow rate of 1.0 ml/min, Column pressure was 30 kpa, Split ratio of 1:2, injection port temp was 250°C, oven temperature was programmed between 40°C and 220°C, detector temp was 250°C, nitrogen carrier gas, BP-5 column and detection by flame ionization detector has been developed. A satisfactory retention time was obtained for methylene chloride (5.40 min), isopropyl alcohol (5.72 min) and butyl acetate (16.13 min). Linearity of the methylene chloride, isopropyl alcohol and butyl acetate was obtained in the range of 1.058484 mg to 5.29284 mg, 0.627284 m g to 3.13684 mg and 0.718484 mg to 3.59284 m g respectively. To ensure accuracy of the method the percentage recovery studies were carried out. Analytical parameters like Limit of Detection, Limit of Quantitation, Precision, Specificity, Ruggedness and Robustness were calculated and full statistical evaluation has been carried out. The developed method has been applied for the quantification of organic volatile impurities in non- aqueous film coated marketed formulations.

GP$_{28}$ A HPLC method for the simultaneous estimation of paracetamol, chlorpheniramine maleate, phenylephrine and caffeine in formulations

M. Senthilkumar*, S. Jayaseelan, R. Gopinath, M. Vasudevan, J.S.K. Nagarajan and B. Suresh.

J.S.S. College of Pharmacy, Ootacamund 643 001, (TN)

Paracetamol is chemically 4-acetamide phenol, it is used as potent antipyretic and analgesic, Chlorpheniramine maleate is chemically (RS)-3-(4-chloro phenyl)-3(2-pyridyl) propyl dimethyl amine hydrogel maleate is used as potent anti histamine. Phenylephrine HCL is chemically (R)-1(3-hydroxy phenyl)-2 methyl amino ethanol hydrochloride used as Anti-nasal decongestant and mydriatic. Caffeine is chemically 3, 7-dihydro-1, 3, 7-trimethyl-1-(H) purine-2-6-di one or its mono hydrate. It is used for migraine.

The combination of these four drugs is commercially available as tablet. A literature survey revealed that the there are number of methods have been reported for the estimation of Paracetamol, Chlorpheniramine maleate, Phenylephrine and caffeine individually or in combination with other drugs. However, there is no method reported for the simultaneous estimation of these two drugs in tablet. The validation of the proposed method was also carried out. A Shimadzu® HPLC system was used for the analysis. The method was carried out using Stationary phase Kromasil C_{18} (25 cm x 4.6 mm i.d., 5µ) column with a Mobile phase consisting of Acetonitrile: Phosphate butter (pH 6.0) (10:90 v/v) at a flow rate of 1.0 ml min^{-1}. A Rheodyne® 7725i injector with a 20 µl loop was used for the injection of samples. The SPD-M10 Avp Diode array detector was used to detect the drugs at 220 nm and CLASS VP data station was used to process the Chromatograms. The mobile phase was filtered through a 0.2µ membrane filter and degassed. The separation was carried out at room temperature of about 20±2° C.

GP$_{29}$ Quantitation of valdecoxib in human plasma by HPLC with UV detection using liquid-liquid extraction

S. Wishu, K.N. Vishwottam, M. Koteshwara and N.V.S. Ramakrishna

Biopharmaceutical Research, Suven Pharmaceuticals Ltd, Serene Chambers, Road #7, Banjara Hills, Hyderabad - 500034, India.

Valdecoxib, Rofecoxib, HPLC-UV.

A simple, sensitive and specific HPLC method with UV detection (210 nm) was developed and

validated for quantitation of Valdecoxib (I) in human plasma, newest addition to the group of nonsteroidal anti-inflammatory drugs. It is a highly selective cyclooxygenase-2 inhibitor, which has been recently approved by the US FDA for treatments of rheumatoid arthritis, osteoarthritis and pain. The analyte and a structural analogue internal standard (Rofecoxib, II) were extracted from plasma by liquid/ liquid extraction with diethyl ether-dichloromethane (70:30, v/v) using a Glascol Multi-Pulse Vortexer. The chromatographic separation was performed on reverse phase ODS-AQ column with a mobile phase of water-methanol (47:53, v/v). The lower limit of quantitation was 10ng/ml, with a relative standard deviation of less than 20%. A linear range of 10 to 500 ng/ml, was established with linear correlation coefficient better than 0.99. This HPLC method was validated with the precision for between-batch and within-batch being 1.27 to 7.45% and 0.79 to 6.12% respectively, and the accuracy for between-batch and within-batch being 0.74 to 7.40% and -0.93 to 7.70% respectively. Frequently coadministered drugs such as paracetamol, ibuprofen, caffeine, aspirin, nicotinamide, ampicillin, amoxicillin etc., did not interfere with the described methodology. To date no simple HPLC method has been reported in the literature for Valdecoxib quantitation in human plasma. This method provides information about the stability of Valdecoxib both in plasma and during method processing (autosampler), which is a clear advantage for quantifying a large number of plasma samples for pharmacokinetic and bioequivalence studies in patients and healthy volunteers.

GP$_{30}$ Evaluation of p-Phenylene diamine and chemical investigations of some marketed hair dye formulations

Ankit V. Patel*, R.A. Fursule, S.B. Gokhale, S.R. Bakliwal

R.C. Patel College of Pharmacy, Karvand Naka, SHIRPUR Dist. Dhule 425405

The consumption of various hair dye formulations in the cosmetic market is increasing everyday. In general the trend of using herbal products where ever available, herbal hair dyes are not exception for safety purposes, since the people are health conscious. It has been found that chemical dyes are mixed with herbal hair care products and wrongly advertised and labeled as herbal dyes. It is the need of the hour to investigate these claims, as these dyes usually contain p-Phenylene diamine (PPD), 2-5 di-amino toluene sulphate (DTS) and 2-nitro 4-phenylene diamine (ONPPD) which is harmful, causing skin disease.

Hence, various hair dyes formulations were purchased from the local market and investigated as per the methods given in standard books such as Indian standards (determination of pH, arylamine content, hydrogen peroxide content were carried out).

The investigations resulted into satisfactory PPD content in the three dye formulations out of five, while two were found to contain more than the permissible limits. The PPD content was also verified by using reported HPLC method. pH and peroxide content for (D) was found to be within limit. But in the formulation B and C_1 PPD content were found to be 4.532% and 4389% which crosses the permitted limit. Whereas arylamine content was found to be within the limit in all formulation ranging from 2.378% to 3.877%.

GP$_{31}$ Colorimetric determination of gatifloxacin in tablets

Gandhimathi. M*, Ravi T. K, Susheel John Varghese & T. Sheela rani

* Department of Pharmaceutical Analysis, College of Pharmacy, SRIPMS, Coimbatore- 641 044

A colorimetric method to determine gatifloxacin from tablets is proposed. This method is based on the reaction of gatifloxacin in 0.1 N NaoH, ceric ammonium sulphate (CAS) and MBTH (3-methyl - 2 - benzothiazolinone hydrazone hydrochloride to form a green colored complex. The absorbance was found out at 452 nm. The method was optimized for strength, volume of reagent and order of addition of reagent The linearity was found to be 10-30 mg/ml. The method is completely validated for reagents, stability, linearity, Sandell's sensitivity and recovery studies. The amount of drug present in the tablet was calculated using calibration graph.

GP$_{32}$ Simultaneous estimation of cetirizine and pseudoephedrine HCl by graphical absorbance ratio method

A. Suganthi, Ajithadas Aruna, H.B. Sivakumar*, Sapna Shrikumar, T.K. Ravi.

College of Pharmacy, SRIPMS. Coimbatore - 44.

Cetirizine[1] and pseudoephedrine[1] combination is indicated for the relief of symptoms of alergic rhinits. Cetirizine is official in EP[2], Pseudoephedrine is official in IP[3], BP[4], USP[5]. But combination is not official in any of the pharmacoepia. So a simple, accurate and economical spectrophotometric method for the estimation of Cetirizine and pseudoephedrine HCl in combined dosage form has been established. The common solvent selected was distilled water. The λ max of Cetirizine (231 nm) and isoabsorptive (241 nm) were determined for mixed standard of Cetirizine and pseudoephedrine. The ratio of absorbances were

plotted against concentrations of mixed standard from 5:1000 to 25:200 µg/ml. A calibration curve was prepared. From the ratio of absorbance of sample formulation, the concentration of Cetirizine and pseudoephedrine were directly measured from calibration curve without prior separation.

The percentage studies were conducted to prove the accuracy, prescision, suitability and reproducibility of the method. The interference studies were also performed with common excipients like talc, starch, magnesium stearate and lactose used in tablet formulation. It showed there was no interference. As the method is less time consuming and does not involve any extensive calculation, this can be employed for routine analysis of drug in combined dosage forms using simpler instrument.

GP 33 Bioanalytical method development and validation of pantoprazole

Sajjad S*, Venktesh G, Ravisankar S, S.M. Vasudevan, B. Suresh

J.S.S. College of Pharmacy, Ootacamund 643 001, (TN)

Pantoprazole is chemically 5-(difluromethoxy)-2-{[(3,4-dimethoxy-2-pyridinyl)methyl]sulfiny1}-1H-benzimidazole sequihydrate sodium. Pantoprazole is a proton pump inhibitor (ppi) that suppresses the final step in gastric acid production by forming a covalent bound to two sites of the (H+,K-) ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect is dose related and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding of the (H+,K-) ATPase results in the duration of anti-secretory effect that persists longer than 24 hours.

The present work describes a reversed phase HPLC method for estimation of Pantoprazole. A Shimadzu® HPLC system was used for the analysis. The method was carried out on Stationary phase Phenomenex Luna column (C_{18}, 25 cm x 4.6 mm i.d, 5µ) with a mobile phase of Triethyl amino solution (pH 7.0) and acetonitrile solution with a solvent ratio 65:35% v v at a µ injector of 20µl loop. The SPA-M10 Avp Diode array detector was used to detect the drug at 289 nm. The CLASS VP data station was used to process the Chromatograms. The mobile phase was filtered through a 0.2 membrane filter and degassed. The separation was carried out at room temperature of about 20±2° C. The validation of the method was carried out using ICH and FDA guidelines.

GP 34 A sensitive HPTLC method for the estimation of swertiamarin from enicostemma littorale blume, swertia chirata (Wall) clarke and formulations containing E. Littorale

Santosh L. Vishwakarma*[1], Milind S. Bagul[2], M. Rajani[2]and Ramesh K. Goyal[1]

1. Department of Pharmacology, L.M.College of Pharmacy, Ahmedabad-380009
2. Pharmacognosy and Phytochemistry Department, B. V. Patel Pharmaceutical Education and Research Development Center, Thaltej, Ahmedabad - 380054..

Swertiamarin, a secoiridoid glucoside present in the members of *Gentianaceae*. It has antidepressant and anticholinergic activity and hence can be used as a biomarker. We developed a simple HPTLC method for the quantification of swertiamarin which can be used for the analysis of plant materials and formulations for swertiamarin content. The method was validated for precision repeatability and accuracy. The method was found to be precise with RSDs for intraday in the range of 0.68 to 0.85 and interday in the range of 0.71 to 1.03 for two different concentrations. Instrumental precision and repeatability of the method were found to be 0.95 and 0.69 (%CV) respectively. Accuracy of the method was checked by recovery study conducted at two different levels and the average percentage recovery was found to be 100.13 %. The method was used for the estimation of swertiamarin content in whole herb of *E. littorale* and *S. chirata* and in herbal formulations containing E. littorale as one of the ingredients. The method required no clean-up of the sample extracts prior to TLC and swertiamarin well resolved (R_F 0.51) in the presence of other components of the sample extracts in a solvent system ethyl acetate-methanol-water (7.7 + 1.5 + 0.5, v/v). The proposed HPTLC method for the estimation swertiamarin was found to be simple, precise, specific, sensitive and accurate and can be used for routine quality control of raw materials as well as herbal formulations. The method was found to be suitable for quantification of swertiamarin from samples containing varying amounts ranging from 0.15 to 7.7 % w/w. E. littorale whole plant was found to be one of the rich sources of swertiamarin (7.7 % w/w).

GP 35 Development and statistical validation of spectrophotometric method for analysis of clozapine in pharmaceutical formulations

N. B. Gaikwad, Y. N. Gavhane*, S. V. Thakkar and B. S. Kuchekar.

Government College of Pharmacy, Vidyanagar, Karad-415124, MS, India.

Clozapine is an atypical neuroleptic drug. It interferes with binding of dopamine at D1 and D2 receptors in CNS. After oral administration it is rapidly and almost completely absorbed. Chemically it is 8-chloro-11-(4-methyl-1-pierazinyl)-5H-dibenzo(b,e)(1,4) diazepine.

Present work describes four simple, precise, validated and sensitive methods for the estimation of clozapine in pharmaceutical formulations. The methods are based on the reduction of ferric ions in ferric nitrate to ferrous ions by the drug, which further in presence of potassium ferricyanide (Method A) and potassium dichromate (Method B) produces chromogens measured at 712 nm and 714 nm respectively. Method C estimates drug in its bulk and dosage form using cerric ammonium sulphate and 3-methyl-2-benzothiazolinone hydrazone hydrochloride (MBTH) reagent forming nitroxide type of compound giving red colored complex measured at 508 nm. Method D quantitates the drug in ultraviolet region at lmax equal to 241 nm.

The proposed methods determine clozapine in concentration range of 10 - 40 mg / ml with correlation coefficient of 0.9983 for Method A, 90 - 130 mg / ml with correlation coefficient of 0.9932 for Method B, 10 - 150 mg / ml with correlation coefficient of 0.9983 for Method C and 2.5 - 35 mg / ml with correlation coefficient of 0.9994 for Method D. The molar absorptivity and sandal's sensitivity values indicated good sensitivity of the methods. The % RSD values were calculated as 0.12 for Method A, 0.06 for Method B, 0.05 for Method C and 0.07 for Method D. The stability of chromogen was established for 1 h, 1 h and 1.5 h for Method A, Method B and Method C respectively. The methods were statistically evaluated for accuracy and precision. Recovery study was performed and percent recovery values indicated non-interference from formulation excipients. The methods in present investigation can be successfully applied to the determination of clozapine in pure form and pharmaceutical dosage forms with good accuracy and precision.

GP 36 Selective visible spectrophotometric estimation of ambroxol hydrochloride in presence of cetirizine in combined solid dosage form

V. H. Potdar*, S. V. Thakkar and B. S. Kuchekar.

Government College of Pharmacy, Vidyanagar, Karad-415124, MS, India.

Ambroxol is a metabolite of bromhexine and is administered as the hydrochloride salt. It is used in a variety of disorders including chronic bronchitis, cystic fibrosis and infant respiratory disorder syndrome. Chemically ambroxol hydrochloride is 4[[(2-amino-3, 5-dibromophenyl)-methyl] amino] cyclohexanol hydrochloride.

Present work describes simple, precise, validated and sensitive method for the estimation of ambroxol in presence of cetirizine in combined tablet dosage. The method estimates drug in its bulk and dosage form using ferric nitrate and 3-methyl-2-benzothiazolinone hydrazone hydrochloride (MBTH) reagent forming nitroxide type of compound giving red colored complex measured at 508 nm.

The proposed method determines ambroxol hydrochloride in concentration range of 6 - 90 mg / ml with correlation coefficient of 0.9973. The molar absorptivity and sandal's sensitivity values indicated good sensitivity of the method. The regression equation for ambroxol hydrochloride was found to be y = 0.0073, x = 0.019. The % RSD values were calculated as 0.28. The stability of chromogen was established for 1.5 h. The method was statistically evaluated for accuracy and precision. Recovery study was performed and percent recovery values indicated non-interference from formulation excipients. The method in present investigation can be successfully applied to the determination of ambroxol hydrochloride in pure form and in combined dosage forms in presence of cetirizine with good accuracy and precision.

GP 37 HPLC method for LABETALOL - an antihypertensive drug

Asgar Ali, Saqib Zafar, Shoaib Ahmad and M. Aqil

Faculty of Pharmacy, Jamia Hamdard, New Delhi 110062

Labetalol HCl (2-hydroxy-5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl) amino]ethyl] benzamide hydrochloride) is an important drug with α - and β - adrenoreceptor antagonist actions and clinically used as antihypertensive drug. The blockade of

α-receptors in periphery leads to a fall in systolic as well as diastolic blood pressure but a reflex increase in cardiac rate and cardiac output (mediated through baroreceptors) is prevented by stronger β-receptor blockade action. The present study was conducted with a view to establish the HPLC method using C_{18} column (300x 4.6mm) for labetalol HCl so that it can be used for quantification of this drug. The HPLC method for determination of labetalol HCl has been developed on binary pump Shimadzu HPLC using C_{18} column (300x 4.6mm) using 0.01 M ammonium phosphate buffer : methanol (40:60) as the mobile phase at a flow rate of 2 ml/min. The drug was detected at 205 nm using UV-Visible detector. 25 ml of the freshly prepared samples of 1, 2, 5, 10, 15 and 20 mg/ml labetalol were injected into the sample port of HPLC instrument using the Hamilton microliter syringe. The retention time of labetalol HCl has been found to be 2.417 and the minimum amount of the detectable drug is 10 mg/ml. It is proposed to utilise this method for quantitative estimation of labetalol HCl in transdermal drug delivery systems and in serum samples.

GP 38 A stability indicating HPLC assay method for cefadroxil

Mehta V. B.*, Wadhwani A. R., Prabhu N.B. and Amin P. D.

Pharmaceutical Division, Institute of Chemical Technology, (Autonomous), University of Mumbai, Mumbai-400019

A stability indicating RP-HPLC assay method was developed and validated for Cefadroxil, a cephalosporin antibiotic used in the treatment of respiratory tract infections. The drug was eluted through Spherisorb ODS2 RP-18 (5µm) column (250 x 4.6 mm i.d.) using the mobile phase 0.05M phosphate buffer: acetonitrile (pH 5.00) (95:5) at a flow rate of 1.0 ml/min. The detection was carried out at λmax of 230 nm.

The developed method was found to give good resolution between the drug (Rt = 5.8 min.) and its degraded products (oxidative degradation product: Rt 2.68 min. and 3.11 min., acid-catalyzed degradation product: Rt 7.66 min., base-catalyzed degradation product: Rt 3.00 min., 9.35 min. and 13.02 min.). Linearity was observed in the concentration range of 1-10 µg/ml (correlation coefficient 0.999). The developed method had good precision and accuracy as evidenced by the low RSD values (<2%). The limit of detection and the limit of quantitation were found to be 35.94 ng/ml and 402.5 ng/ml respectively. The drug was found to be stable in solution when analyzed at 0, 6 and 24 hours. Excellent recovery was obtained at the levels studied (98-102%). No interference was observed from the excipients in the formulations.

The developed HPLC method is precise, accurate and stability indicating and may be used for the quantitative estimation as well as the assessment of the stability of Cefadroxil as bulk drug and in its dosage forms.

GP 39 Simultaneous estimation of methocarbamol and nimesulide in tablet by HPTLC

Chatki P. K.*, Manwar J. V. and Tajne M. R.

Department of Pharmaceutical Sciences, Nagpur University, Nagpur-440 033.

A combined dose tablet containing Methocarbamol, a centrally acting muscle relaxant and Nimesulide, anti-inflammatory, analgesic and antipyretic is used in management of painful muscle spasms.

The present work describes a simple, precise and accurate HPTLC method for their simultaneous estimation in tablet.

The chromatographic separation of drug was done on HPTLC precoated silica gel $60GF_{254}$ aluminum plates using mixture of toluene : 0.05M methanolic ammonia (8:2) as mobile phase. The separated spots were densitometrically evaluated at 276 nm using CAMAG-TLC Scanner-III with CAT's 4.0 version software. The experimental parameters like band size of spot applied, chamber saturation time, solvent front migration, slit width etc. were critically studied and optimum conditions were evolved. The two drugs were satisfactorily resolved with Rf values 0.41 and 0.66 for Methocarbamol and Nimesulide respectively. Their linearity ranges were 1-10ìg for Methocarbamol and 0.1 - 1.0 ìg for Nimesulide.

The mean results of estimation in tablet were 100.28±0.812% (by height) and 98.80±0.739 (by area) for Methacarbamol and 99.67 ±0.918% (by height) & 99.31±0.308 % (by area) for Nimesulide and their recoveries from the tablet matrix determined by standard addition method were 99.93±1.69% (by height) & 99.66±1.37% (by area) and 99.95±1.27% (by height) and 99.64±1.30% (by area) respectively.

The accuracy and reliability of the proposed method was ascertained by evaluating various validation parameters like accuracy, precision, specificity, linearity & range and ruggedness.

The method can be used in routine simultaneous estimation of Methacarbamol and Nimesulide in tablet.

GP 40 A HPLC determination of betacarotene in the fruit juice of *Passiflora edulis* Sims

Sapna Shrikumar, Athem Sait*, V. Kavitha, A. Suganthi, T.K. Ravi

Department of Pharmaceutical Analysis, College of Pharmacy, SRIPMS, Coimbatore-44.

Passiflora edulis Sims is available in purple and yellow fruited form. The juice from the ripe fruit of *Passiflora edulis* Sims is highly nutritious and contains ascorbic acid and is rich in carotene and acid content. The plant is used as antispasmodic, narcotic, sedative, anthelmintic, blood pressure reducers, expectorant and the fruits are a good source of vitamin C. The pulp of the fruit is used as a stimulant and tonic.

The ripe fruits of Passiflora edulis Sims were collected from the inner region of Kerala (Kottayam) in the month of June and concentrated by vacuum distillation below 40°C. The total carotenoids were extracted from the dried juice of the ripe fruits of *Passiflora edulis* Sims and stored at 0°C to prevent oxidation. The standard Beta-carotene was procured from Hi-media Laboratories, Mumbai. An isocratic HPLC system (Shimadzu) consisting of LC-10AT liquid pump, SPD-10AUV/Vis detector, a ODS C-18 RP-column (4.6mm I.D ´ 25cm), 25ml Hamilton injecting syringe and window based single channel software was used.

The method involves separation of Beta-carotene using an isocratic mobile phase consisting of acetonitrile, methylene chloride and methanol in the ratio of 82 : 12 : 16 at 436 nm using photo diode assay detector. The sensitivity was found to be 0.25mg. The Beta-carotene content of 3.21%w/w was observed in test sample.

The calibration curve was linear in the range of 0.25 to 2.50 mg with correlation co-efficient of 0.987998 indicating good linearity between concentration and area. The method provides good resolution and separation of Beta-carotene from other constituents of total carotenoids. An average recovery of 99.08% w/w shows the reliability and suitability of the method. The proposed HPLC method is rapid, simple and accurate for quantitative monitoring of Beta-carotene in *Passiflora edulis* fruit and can be used for its standardization with respect to active principle.

GP 41 Spectrophotometric estimation of carbocysteine in capsule formulation

Bala Krishna. B.*, Sanjay Pai P.N. and Gopalkrishna Rao

Department of Quality Assurance, Al-Ameen College of Pharmacy, Bangalore 560 027

A simple, sensitive, reproducible and economical method for the estimation of Carbocysteine in capsule formulations was developed using Carbon disulphide - Pyridine - Isopropyl alcohol (CPI) reagent. The accuracy and the effectiveness of the proposed method was proved by comparison of the result with that of the official potentiometric method.

The absorption maxima of the condensed product with CPI that yielded an orange yellow chromophore was 413 nm. The beer's law concentration range was established to be 10 - 80 mcg/ml. The color was stable for over 90 min with Sandell's sensitivity of $10.1867' 10^{-2}$ mcg / cm^2/ 0.001 absorbance units and molar absorptivity of $3.27'10^4$ $mole^{-1}$ cm^{-1}. The regression equation for the proposed method is calculated by least square method as Y= a + bx, where x is the concentration of the substance in mcg and Y is the absorbance at specific l max, 0.0001 is the intercept (a) of the linear line and $9.81' 10^{-3}$ the slope (b) of the line. The standard deviation of 0.2308191 indicated accuracy and reproducibility in color development. The method was extended for determination of carbocysteine in capsule formulation. It was observed that the results obtained were comparable to that of the label claim, and data generated when the same formulation was analyzed by official potentiometric method. The recovery studies of the standard when performed on the preanalyzed formulation gave percentage recovery of 95.0% - 100.6 % indicating practically no interference of formulation excipients with the proposed method.

GP 42 Microwave assisted quantitative estimation of drugs

Shrishaillappa Badami, Natasha Joseph C*, Vijeesh Govindan, Bromine Thomas, Elna Merilla Bose, Gensi Kuriakose and Suresh B.

J.S.S. College of Pharmacy, Rocklands, PB.No:20, Ootacamund - 643 001, (T.N.)

Traditional chemistry laboratories used large quantities of toxic chemicals and solvents to perform reactions, exposing the students and the environment. Microwave technique is presently being used as a tool of green chemistry. In order to utilize the microwave technique for quantitative estimation of certain drugs, the present study was under taken. The quantitative estimation of aspirin, calcium carbonate, aspirin in aspirin caffeine tablets were carried out as per the conventional standard procedures and also by microwave technique. The irradiation was carried out at different intensities and for various durations. After each experiment the drug was analyzed quantitatively. The conditions were fixed based on the quantitative results obtained in several experiments.

The conventional procedure for the assay of aspirin gave 96.93% purity after 19 minutes heating. However, the standardized microwave technique

involves heating in a microwave oven at 40% intensity for 2 min duration gave 100.35% purity. In the assay of aspirin in aspirin - caffeine tablets the conventional method of heating for 30 min gave 70.11% purity. However, the assay under microwave irradiation at 950W intensity and for 18 min duration gave 74.17% purity.

From the results it is clear that the microwave method can be used for the quantitative analysis of organic molecules. The microwave method is a fast and cheap technique and can routinely be used in laboratories for analysis.

GP 43 Estimation of valdecoxib and counter irritants for novel emulgel using new, sensitive and precise HPLC method

Rajendra S.T.* and Vavia P.R

Mumbai University Institute of Chemical Technology, N. P. Marg, Matunga, Mumbai - 400 09

Valdecoxib (VAL) is a highly potent Nonsteroidal Anti Inflammatory Drug (NSAID). It has become a hotcake amongst other NSAIDs in pain management regimen. The clinical studies had proved its effectiveness at quite low oral dose as compared to Ibuprofen and Diclofenac.

We have developed a Novel Emulgel containing VAL and few counterirritants. The literature survey revealed that there is no report for simultaneous estimation of VAL. Methyl Salicylate (MS) and Capsaicin (CAP).

A simple, precise and selective HPLC method has been developed for simultaneous determination of the above-mentioned ingredients in VAL Emulgel. The column used was Waters C18 ODS 4 x 250 mm (5µ packing). The components were eluted using the mobile phase Acetonitrile: Phosphate Buffer (40:60) at a flow rate of 1 ml/min. The wavelength of detection used was 280 nm. Throughout the analysis, the temperature of column was maintained at 30° C. The elution order observed was, VAL (8.0 min), MS (13.25 min) and CAP (23.28 min).

The proposed chromatography method gave good resolution between drug and two counterirritants. The linearity of the method was established in the range of 2-24 µg/ml (r=0.9998) for VAL, 50-200 µg/ml (r=0.9999) for MS and 2-20 µg/ml (r=0.9998) for CAP. Chromatographic limit of detection (LOD) for VAL, MS and CAP were 0.36 ng/ml, 3.71 ng/ml and 0.58 ng/ml respectively. The limit of quantification (LOQ) for VAL, MS and CAP were 1.20 ng/ml, 10.55 ng/ml and 1.93 ng/ml respectively. The method was also validated for accuracy, precision, ruggedness and recovery. The proposed method showed excellent precision with a low % RSD of <2.

The described method was found to be simple, precise, sensitive, accurate and reproducible.

GP 44 Developing and validating sensitive analytical mehtod for the determination of nifedipine and its impurity in trace level

P.D. Hamrapurkar, Dhananjay Sable*, Tarun, Archana, Leena

K.M. Kundnani College of Pharmacy, Worli Mumbai - 400 018.

The quality and safety of pharmaceuticals can significantly be affected by the presence of impurities consequently, the testing and establishment of limits for impurities in Active Pharmaceutical Ingredients (APIs) have become important initiative by both federal and private organization.

Nifedipine an anti-anginal drug acts by blocking calcium channel.

The drug and its two related impurities (viz . Nitrophenyl pyridine analogue, Nitrosophenyl analogue) arising from its synthesis and degradation have been charecteized by using UV , IR, mass spectrometry , NMR and Thermal analysis.

The analytical method was developed and estimated for the quantitative analysis of Nifedipine and its impurity using HPTLC.

The HPTLC was performed on silica gel 60 F 254 E-Merck Germany. The chromatographic conditions were optimized. Among several mobile phases investigated, the solvent system cyclohexane:ethyal acetate(2+3v\v)gave the best separation.

The spot was detected using CAMAG densitometer. The method was validated for accuracy, precision, linearity range.

The C.V. was found to be less than 2 percent. The HPTLC method thus developed was found to be precise & specific for analysis of Nifedipine & its impurities. viz. Dimethyl-2,6-dimethyl-4 (2-nitrophenyl) pyridine-3, 5-dicarboxalate. And Dimethyl 2, 6-dimethyl-4(-2-nitrosophenyl) pyridine-3, 5-dicarboxylate).

GP 45 Simultaneous determination of ciprofloxacin and ornidazole by RP-HPLC

C.N. Nalini*, K. Kavitha and S. Kumaravel

*Department of Pharmaceutical Analysis, C.L.Baid Metha College of Pharmacy, Chennai - 600 096.

A reversed phase HPLC method using Shimadzu HPLC-VP series, LC-10 ATV pump,

SPD10AVP, C18 column has been developed for simultaneous determination of Ciprofloxacin and Ornidazole in marketed tablet formulation. The mobile phase consists of distilled water containing triethylamine and acetonitrile HPLC grade in the ratio of 3:1. The flow rate was maintained at 1 ml/min and the UV detection was done at 277 nm. Linearity coefficients, assay values, recovery studies and repeatability studies showed that the method is accurate and precise.

GP 46 Development and validation of HPLC methods for the Simultaneous estimation of drugs in selected anti-histaminic multicomponent dosage forms

Suresh.P.S*, Venkataraju.D, Sivakumar.SPN, Trinanjan Paul Vasudevan.M,Nagarajan.JSK, Suresh.B

Dept.of Pharmaceutical Analysis, J.S.S. College of Pharmacy, Ooty

Pseudoephedrine sulfate is chemically (1S,2S)-Methylamino-1-Phenyl -1-Prapanol sulfate Which is Nasal Decongestant and treatment of Bronchial Asthma . Fexofenadine HCL is chemically (') -4-{1-hydroxy -4-{4-(hydroxy phenyl methyl)1-piperidinyl) -á-á-dimethyl benzene acetic acid hydrochloride which is antihistaminic drug . The combination of these drug is commercially available as tablets . The Tablet contain 180mg of psuedoephedrine sulphate and 120mg of Fexofenadine HCL . Which is used for the the treatment of allergies for the the relief of symptoms associated with seasonal allergic rhinitis . A literature survey revealed that there are number of methods have been reported for the estimation of Psuedoephedrine sulfate and Fexofenadine HCL and individually or in combination with other drugs . However there is no method reported for the simultaneous estimation of these drugs .Hence present work describes a reversed phase HPLC method for simultaneous estimation of these two drugs in tablets. The validation of the proposed method was also carried out . A shimadzu HPLC system was used for the analysis.The method was carried out on a Kromasil C_{18} (25cm 4:6 mm i:d 5m)column with a mobile phase consisting of Acetonitrile & 0.5%v/v triethylamine (P^H adjusted to 3.5 using orthophosphoric acid) in the ratio 45:55 at a flow rate of 1.2 ml /min. A Rheodyne 7725 injector with a 20ml loop was used for the injection of samples. The SPD-M10 AVP photodiode array detector was used to detect the drugs at 220nm and class VP data station used to process the chromatograms. The mobile was filtered through a membrane filter 0.2m and degassed. The separation was carried out at room temperature of about 20+/-1°C.

GP 47 A new method for Calorimetric estimation of β-Artemether

Jain Hayesh M.*, Joshi Medha, Patravale Vandana B.

Pharmaceutical Division, Institute of Chemical Technology, (Autonomous), University of Mumbai, Mumbai -400019

Artemether is a new semisynthetic antimalarial drug derived from natural product artemisinin (also known as quinghaosu) which is particularly effective against either the chloroquine resistant or the mefloquine resistant strains of *Plasmodium falciparum.* The chemical structure of Artemether, displays and endoperoxide bridge and lacks UV chromophore appropriate for its routine measurement using UV detection, but it can be readily reduced to α, β - unsaturated decalone and α, β - unsaturated aldehyde, by acid decomposition, which has a specific absorption peak at 254 nm.

Reported methods reveal that the drug has been analyzed by HPLC with UV detection after hydrolysis with acid, HPCL with electrochemical detection, or by HPLC with electrochemical detection in a reductive mode.

The objective of the present investigation was to develop a calorimetric method for estimation of β - Artemether as bulk by colorimetry using Schiff's reagent. A simple calorimetric method for the determination of β - Artemether by combining the aldehyde group of acid decomposed product with Schiff's reagent was developed for routine 553 nm. Linearity of the standard was observed between 100- 500 mcg/ml with r= 0.9998 and r.s.d of less than 2. The intensity of colour was optimized by varying the concentration of acid (0.5N, 2.5N, 5N HCL), amount of acid (0.5 ml. 1 ml, 2ml HCL), and amount of Schiff's reagent (I ml, 2ml) to give violet chromogen, which was found to be stable for more than 6 hrs.

The proposed method for the estimation of β - Artemether is simple, sensitive, precise and can be employed in routine quality control analysis.

GP 48 A HPLC method for the simultaneous estimation of terbutaline sulphate and guaiphenesin

R.Rajesh.*, R.Gopinath, M. Vasudevan J.S.K. Nagarajan and B. Suresh

J.S.S. College of Pharmacy, Ootacamund 643 001. (TN)

Terbutaline sulphate is chemically (RS)-2(tert-butyl amino)-1-(3,5-dihydroxy phenyl) ethanol sulphate, it is a direct acting symptomimetic with predominantly

beta adrenergic activity and a selective action on beta -2 receptors. Guaiphenesin is chemically (RS)-3-(2-methoxy phenoxyl) 1-2-propane diol it is used as symptomatic relief of respiratory conditions.

The combination of these two drugs is commercially available as tablet. A literature survey revealed that there are number of methods have been reported for the estimation of Terbutaline and Guaiphenesin, individually or in combination with other drugs. However, there is no method reported for the simultaneous estimation of these drugs. Hence the present work describes a RP-HPLC method for simultaneous estimation of these two drugs in tablet. The validation of the proposed method was also carried out was filtered through a 0.2m membrane filter and degassed. The separation was carried out at room temperature of about 20±2 °C.

A Shimadzu® HPLC system was used for the analysis. The method was carried out using Stationary phase Hypersil C_{18} (25cm x 4.6mm i.d., 5m) column with a Mobile phase consisting of Phosphate buffer(pH3.5):Methanol (60:40 v/v) at a flow rate of 1.0 ml min^{-1}.A Rheodyne® 7725i injector with a 20 ml loop was used for the injection of samples. The SPD-M10 Avp Diode array detector was used to detect the drugs at 220 nm and CLASS VP data station was used to process the Chromatograms. The mobile phase

GP 49 Simultaneous estimation of L-Lysine hydrochloride and DL-methionine in multivitamin oral dosage form by HPTLC

Singh R. A. *, Singh Amrita, Kumar Robin Arora Saurabh

Arbro Pharmaceuticals Ltd., 4/9, Kirti Nagar Industrial Area, New Delhi 110 015

L-Lysine Hydrochloride and DL-Methionine, both are essential amino acids. A number of products containing both L-Lysine Hydrochloride and DL-Methionine are available in the market as liquid oral dosage forms. A few colorimetric methods are available for individual determination of amino acids but not much work has been done for their simultaneous estimation in combined dosage forms. A simple, accurate and reproducible High Performance Thin Layer Chromatographic (HPTLC) method has been developed and validated for simultaneous estimation of L-Lysine Hydrochloride and DL-Methionine in Multivitamin Liquid oral formulations. The separation was obtained using 1-Propanol: water: Acetic acid (70: 30: 2 v/v) as mobile phase and HPTLC precoated plates G60 F 254 (Merck) The chromatograph was dried and sprayed with Ninhydrin solution and scanned at 550 nm (Iso-absortpion point for quantification) using Camag II Densitometer. The resolution of both the amino acids was good having Rf values 0.17 and 0.65 respectively. Both the drugs were found linear in the range of 10-100 mg/ml. The results obtained using the proposed method revealed that the amount observed is in good agreement with the labelled claim and standard deviation (SD) was satisfactorily low indicating the reproducibility and accuracy of the method.

GP 50 Simultaneous estimation of ofloxacin and ornidazole in pharmaceuticals dosage form by RP-HPLC

Singh R. A.*, Kumar Dinesh, Kumar Robin, Arora Saurabh

Arbro Pharmaceuticals Ltd., 4/9, Kirti Nagar Industrial Area, New Delhi 110 015

A simple, reproducible and rapid method for the simultaneous determination of Ofloxacin and Ornidazole in pharmaceutical dosage form by reversed phase High Performance Liquid Chromatography has been developed and validated. The separation was achieved using a mixture of 75 volume of 0.025M phosphoric Acid, previously adjusted with Triethanolamine to pH of 3.0 + 1 and 25 volume of Acetonitrile as mobile phase. The column used, was a Lichro Cart RP-18e (5mm)(250 x 4.0 mm) of Merck Germany, operated at ambient Temperature with a flow rate of 1.0 ml / min and U.V. detection at 303 nm. The retention time of Ofloxacin and Ornidazole was about 4.0 and 8.0 minutes respectively. The composition and polarity of the mobile phase was found to be suitable for individual drugs as well as for the mixture. Linearity range for both the drugs was found in the range of 10mg to 100mg/ml. For further validation of this method a recovery study was also conducted by adding known quantity of drugs in the pre-analysed test solution and the percentage recovery was calculated subsequently in each case. The percentage recovery for both the drugs was found to be between 99.0 to 101.0% w/w. Proposed method was found to be accurate, simple, rapid and can be conveniently used for routine analysis.

HP$_1$ *In-vitro* screening of selected medicinal plant extracts for their antiviral activity against polio virus type-I

P.Vijayan, S.A. Dhanaraj, Yadav Vivek*, K.Ashish and B.Suresh

Department of Pharmaceutical Biotecnology, J.S.S. College of Pharmacy, Rocklands,Ooty.

Many compounds have potent antiviral activity on cell culture, but only about 1% of these compounds is active in animals. Out of those that have good antiviral activity and acceptable toxicity in animals, only a few antiviral drugs are active in human.

Screening of the plant extract can provided valuable information about the bioactive compound present in them, which may be effective against the viral diseases, hence it was decided to exploit the potential of some of the medicinal plant extract.

In the study we have selected the different plant parts of *Callistemon citrinus (Myrataceae)*, *Euphorbia hirta (Euphorbiaceae)* and *Erythrina indica (Fabaceae)* based on their Ethanopharmcological use.

Extract was prepared by Soxhlation process using methanol as the solvent and the volatile oil was extracted by Clavenger's apparatus by hydrodistillation.

The methanolic extract and volatile oil of the different parts of above plants were challenged with Poliovirus Type-I at different concentration, HEp2 cell culture was used as substrate for virus challenge.

Antiviral screening was done based on the inhibition of virus induced Cytopathic effect (CPE). Plaque reduction assay and virus yield reduction assay.

In cytopathic effect (CPE) inhibition assay methanolic extract of *Euphorbia hirta* showed 100% protection of cells *Erythrina indica* protect the cells only when challenged with 10 $TCID_{50}$ of virus.

HP$_2$ Screening of soil samples for exo-inulinase producing microorganisms

Aravind Kumar. M., Mahalaxmi Rathnanand and *J.Venkata Rao

College of Pharmaceutical Sciences, Manipal 576104, Karnataka.

Soil samples from Manipal and nearby places were screened for organisms with exoinulinase activity. Out of four isolates, which are designated as MPL, SLP, PKL and ALUR, two isolates viz., MPL and SLP showed exoinulinase activity. These two isolates were subjected for further studies for maximizing the enzyme activity. Optimization parameters were substrate concentration, nitrogen source and pH. Results indicated that, at pH 6.5 with a substrate concentration of 3% Inulin and sodium nitrate as nitrogen source and after 5d of incubation, both isolates showed maximum yield of fructose and enzyme activity. For MPL, the maximum yield of fructose was 240.7 mg/100ml and for SLP 237.8. The enzyme activity for SLP was found to be 0.35 lu ml^{-1}. The isolates MPL and SLP were identified as *Aspergillus foetidus* (MTCC 4873) and *Trichoderma harzianum* (MTCC 4874) , respectively. Yield of fructose by these two isolates were compared with that of the standard organisms i.e. *Penicillium purpurogenum* 760, *Penicillium purpurogenum* 713, *Aspergillus fumigatus* and *Cladosporium.*

HP$_3$ Immobilization studies on *Capsicum annuum* Lin

Singh Shashank* Bodla R.B Agrawal S.S

College of Pharmacy, Pushp Vihar, Sector 3, New Delhi 17.

Plant cell culture have been utilized for the production of natural product particularly those of secondary metabolites like *Shikonin, nicotine* from *Lithospermum erythrorhion* and *Nicotiana tobaccum* respectively the accumulation of these secondary metabolites by cell culture techniques is regarded as processes for continous bioproduction of the desired metabolites,the existing cell culture technique seem outmoded indicate a need for new methods of manipulation. The new strategy of using Immobilized cell culture Technology is used in the studies of in *Capsicum annuum* cell culture for bioproduction of its major pungent capsaicin and the oleoresin which are of commercial value globally moreover, therapeutically it has been approved by the US-FDA for its counter irritant and topical analgesic activity. Present work describes optimization and development of immobilized cell suspension of capsicum annuum cells. Seeds of *C.annuum* were germinated aseptically and callus was intiated from hypocotyl explants on Murashige and Skoog (MS) medium supplemented with sucrose ,2,4 D and kinetin in suitable concentration. Cell suspension culture were developed from callus cultures and incubated on a rotary shaker at 90 rev./ min under continuous light of 2000 lux intensity at 25+ 2 °C. These 16 week old cell suspension cell were separated by filtration and suspended in 1.5% (w/v) sodium alginate dissolved in water, and extruded into 0.061 M $CaCl_2$ and incubated in MS liquid medium containing Phytohormones 2, 4 D (9.05mM), Kn (4.60mM). Presence of capsaicinnoids were estimated qualitatively and quantitatively through TLC and GC respectively. Results of freely suspended cells were

compared with the immobilized cells and found that capsainin biosynthesis increased 100 to 700 folds in immobilized cells then freely suspended cells.

HP$_4$ Elicitors stimulated ajmalicine production from *Catharanthus roseus* suspension cultures

Ajay G. Namdeo, M. D. Kharya

Institute of Pharmacy, Jiwaji University, Gwalior. Department of Pharmaceutical Sciences, SAGAR.

Cultures of *Catharanthus roseus* were elicited with the extracts of *Aspergillus niger, Fusarium* moniliforme and *Trichoderma viride*. The effects of elicitor dosage, exposures time and age of subculture on ajmalicine accumulation was studied. Higher concentration of elicitor extract responded positively to C. roseus suspension cultures. Ajmalicine accumulation increased by about three folds when cells treated with *A. niger, F. moniliforme* and *T. viride.* The maximum ajmalicine production (75 mg g^{-1} DW) was observed in cells treated with *T. viride*. Cell cultures were elicited with 5% preparation of *A. niger*, F. moniliforme and *T. viride* and exposed for 24, 48, 72 and 96 hr. for elicitation. Suspension cultures elicited with *T. viride* for 48 hr showed three folds increase (87 mg g^{-1} DW) in ajmalicine contents, whereas, *A. niger, F. moniliforme* synthesized two folds increase in alkaloid and yielded 52 and 56 mg g^{-1} DW ajmalicine respectively. *C. roseus* cells of different age (5,10, 15, 20 and 25 days old) were treated with 5% elicitor of *A. niger, F. moniliforme* and *T. viride* and investigated elicitors activity at different age of cell cultures. Maximum yield 166 mg g^{-1} DW of ajmalicine was synthesized in 20 days old suspension cultures treated with *T. viride*. Longer period of incubation of cell cultures with elicitors adversely affected the ajmalicine synthesis.

HP$_5$ Immobilization of porcine pancreatic lipase on Ion exchange resin

Awate B. P., Trivedi D. A. and Degani M. S.

Pharmaceutical Division, Mumbai University, Institute of Chemical Technology, Matunga, Mumbai -19. Email: msdegani@vsnl.com.

Lipases (Triacylglycerol ester hydrolase E.C. 3.1.1.3) are enzymes, whose biological function is to catalyze the hydrolysis of triacylglycerols.

Lipase catalyzed reactions in organic solvents are becoming increasingly important in enantioselective synthetic chemistry. The commercial application of lipases as biocatalysts for organic syntheses requires simple but efficient methods to immobilize the enzyme, yielding highly stable and active biocatalysts which are easy to recover.

In this project a method to achieve lipase immobilization on an anion exchange matrix was developed. A typical immobilization procedure involves addition of an aqueous solution of lipase to the resin and stirring at low temperature to facilitate adsorption. This method is applicable to wide variety of lipases. Very good adsorption yields were obtained with this procedure.

Studies on the stability of immobilized lipase under reaction conditions revealed good retention of enzymatic activity. Studies have been carried out on parameters like change in pH optima, temperature optima and temperature stability.

It was found that this was a good immobilization method, resulting in reusability of the lipase as a biocatalyst for several re runs.

HP$_6$ Effect of coumarin and its derivative on the immune system

Ramakrishna Raparla*, Gopalakrishnan.S, T.K. Ravi, Sumita Singh

College of Pharmacy, Sri Ramakrishna Institute of Pharmaceutical Sciences, Coimbatore 641 044, TN

As the progress in clinical immunology revealed immune improvement (or) dysfunction associated with allergies, autoimmune disease, infectious diseases and malignancies, it became tempting to develop agents that act on immune system. These are called immunomodulators which could be either stimulatory or suppressive. Coumarin -- 1,2-benzopyran nucleus was found to have immunomodulatory activity. In our study we have evaluated the effect of 4-OH coumarin and warfarin sodium in different concentration (10 to 30 mg/ml) on different immune parameters such as phagocytosis assay, Active T-cell rosette formation (CD2R) and passive haemagglutination. The observations suggest that there was an increase in percentage immunostimulation in phagocytosis assay by 21.42% and 25% using 20 and 10 mg/ml, increase in active T-cell rosette formation with a percent increase of 45 ± 4.5 ($p>0.01$) and 55 ± 2.5 ($p < 0.001$) with 4-OH coumarin and warfarin sodium respectively. There was a two fold increase in anti body tire with 4-OH coumarin. These results indicate that 4-OH coumarin may have immunomodulatory activity.

HP$_7$ Hypocholesteremic effect of fermented pulses

S.A.Dhanaraj, N.Vijaya Shankara Narayanan*, P.Vijayan and B.Suresh

Department of pharmaceutical Biotechnology, J.S.S. College of Pharmacy, Rocklands, Ooty.

The fermentation of pulses using fungal species is a time old process. Pulses are used a lot

nowadays. The fermentation of pulses, is solid substrate fermentation type, and does not employ any fermentor. The fermentation was done using fungal organism *Rhizopus oryzae*. The pulses used for fermentation were Bengal gram, kidney Beans and green Peas. The fermented pulses showed increase in protein and had better antioxidant activity when compared to unfermented pulses. The antinutritional factors like lectins were decreased in the fermented pulses.

The pulses were cleaned and were dehulled and kept overnight in soak water for acid bacterial fermentation. Then they were cleaned and boiled for one hour and cooled and drained. *Rhizopus oryzae* was mixed and kept at 26°C for 48 hours. The cakes formed were extracted with methanol and extract was collected. This extract was used for further studies.

Hypocholesteremic effect was done on Wistar Albino rats. The animals were given high fatty diet for 14 days. Standard drug was given with high fatty diet for the control group. Other groups received 80% methanolic extract of fermented pulses with high fatty diet for 14 days through oral route. A normal group was also maintained which was given saline with normal diet. Blood was withdrawn after 14 days and tested for Total cholesterol, HDL-cholesterol, VLDL-cholesterol, LDL-cholesterol, Triglycerides. The level of Total cholesterol, HDL-cholesterol, VLDL-cholesterol, LDL-cholesterol, Triglycerides were found to be reduced in the animals treated with fermented pulse extracts. The fermented pulses showed decrease in anti nutritional factors and increase in protein content.

HP$_8$ Comparative study of biotransformation of benzaldehyde to L-phenyl acetyl carbinol (L-PAC), by yeast

***M. Ravikumar[1], [2]M.Lashmi Narasu, [1]Yasser Majid, [1]Nazia Zareen**

1. Sultan-ul-uloom college of Pharmacy Road No 3, Banjara Hills, Hyderabad - 34.
2. Center for Biotechnology, IPGSR, Jawarlal Nehru Technologies University, Hyderabad -28, A.P

L-Phenyl acetyl carbinol (L-Pac) is the starting material for chemical synthesis of L-ephedrine and pseudoephedrine hydrochloride, used as decongestant, antiasthmatics and recently reported, used in obesity control. The conversion of benzaldehyde to optically active L-phenyl acetyl carbinol is by yeast fermentation. The typical fermentation raw materials are molasses, which provides a source of hexoses for glycolysis, and benzaldehyde. The pyruvate decarboxylase complex catalyzes L-PAC formation. In the carboligase reaction, pyruvate is decarboxylated to active acetaldehyde, which forms the carbinol product in the presence of benzaldehyde co substrate. Total benzaldehyde is not converted to L-PAC and usually some of the benzaldehyde is reduced to benzyl alcohol. Benzoic acid may also be produced at very low levels.

Production of L-PAC through biotransformation of benzaldehyde by free cells of *Saccharomyces cerevisiae* obtained from fresh commercial grade Baker's Yeast and *Saccharomyces cerevisiae* cells isolated from sugarcane juice were used for the comparative study of biotransformation potential of both strains. L-PAC production by sugarcane juice Yeast (SCY) was found to be 2.1 g/L when compared with standard strain of *Saccharomyces cerevisiae* (BY) which showed 1.58 g/L when potential of Immobilized cells of both standard strains of *Sccharamyces cerevisiae* and Sugarcane Juice isolate of *Sccharamyces cerevisiae* were studied. Immobilised cells of standard strain of *Sccharamyces cerevisiae* showed 1.54 g/L of L-PAC and Sugarcane Juice isolate Immobilised cells strain produced 1.66 g/L. L-PAC. Sodium alginate was used as carrier material for Immobilization process. The fermentation was carried out in shake flasks on rotary shaker (180EPM) for 24 hours.

HP$_9$ Studies on the biochemical and physiological variations between *in vitro* and *in vivo* raised italian millet plant

Kalaskar Mohan G*., Muthusamy V.S. B. Duraiswamy, Subburaj T. & Suresh B.

Department of Pharmacognosy, J.S.S. College of Pharmacy, Ooty.

Millets are the group of plants having tolerance to grow under impoverished condition. *Setaria italica* (L) Beau. is one of the most important millet having high nutritive value. It is not only used as a food crop, but also used for medicinal purposes. Due to tremendous applications, it was included as an economic in the World economic plants list. Plant tissue culture is the science of growing plant cells, tissues (or) organs isolated from the mother plant on artificial media. It is a vegetative method for producing the hygienic and disease-resistant plant. The present work was initiated with the aim of developing protocol for the production of hygienic, disease free genotypes of *S.italica* and biochemical variations such as total soluble sugar, total protein, free amino acid and estimation of chlorophyll-a and chlorophyll-b and total chlorophyll content and physiological variations such as root behavior, shoot elongation and number of shoots etc., between the in vivo and *in vitro* raised plants were investigated. The results of *in vitro* raised plant obtained with a treatment of BAP + KIN (0.4 mg 1^{-1} + 0.2 mg 1^{-1}) was elongation of shoot tip explant, maximum number of shoots and highest shoot length elongation. The treatment with IBA (0.4 mg 1^{-1}) for root behavior showed the maximum number of roots with highest root length. The in vitro raised plant yields comparatively higher amount of biochemical and

physiological constituents than in vivo plant except free amino acid content.

HP 10 Application of human - genome data to cure genetical diseases

Pankaj Arora *, Namita Ahuja, Alok Jain, Rajesh - Katara, Mukesh Gupta Priyanka Mehta.*

B.N. College of Pharmacy, Udaipur (Raj)

Genetical diseases are caused due to change in the genetic make-up of human cell. Genetic make-up of a cell is related to human genome i.e. the complete set of chromosomes and genes of an organism. Genetic diseases can be classified into three classes:

- Chromosomal diseases
- Monogenic disorders
- Multifactorial diseases.

These genetical diseases can be cured with the help of analysis and management of genetical data of a human being.

Gene therapy is a key area in medical research. Gene therapy involves: -

- Gene replacement
- Correction, or
- Augmentation.

Analysis and management of genetic data in scientific databases can be done on three successive levels: -

- Genomic database mining
- Gene expression database mining
- Proteome database mining

Genomics is a scientific discipline, which focuses on the systematic investigation of genomes. Genome database mining is an emerging technology. It is referred to as computational genome annotation i.e. the process by which an uncharacterized DNA sequence is documented by the location along the DNA sequence of all the genes that are involved in genome functionality.

Computational genome annotation consists of two sequential processes: -

- Structural annotation - It is identification of hypothetical gene in a sequence.
- Functional annotation - It is assignment of functions to the predicted genes.

Thus information about human genome obtained from Genome database mining helps to understand the cause of disease and aids to cure it.

HP 11 *In - vitro* free radical scavenging activity of *Phoenix dactylifera*

Vandana Jain, Dr. P.K. Dubey*.

B.R. Nahata College of Pharmacy, Mandsaur (M.P.)

Free radical scavenging activity of different extracts of *Phoenix dactylifera* was studied by various *In-vitro* models. Addition of Alcohol and water extract of *Phoenix dactylifera* was found to scavenge the free radicals of Super oxide generated by photo reduction of Riboflavin ($IC_{50\%}$ 35 µg, and 320 µg respectively). The alcohol extract was found to be more potent as free radical scavenger as compared to that of water extract. however both extracts have failed to show any significant scavenging effect on Dinitro phenyl picryl Hydrazine radicals. These results clearly shows potent *in vitro* antioxidant activity of polar extracts of *P. dactylifera.*

HP 12 Insulin dependent diabetes: are we ready for the war?

Poddar S. S., Rajkumar Dube, Jyoti Panjwani* and Milina Waswani.

K. M. K. College of pharmacy, Mumbai-18.

Diabetes is the third biggest disease in the globe as far as the death due to diseases are concerned. Surveys of the past make it clear that shortly we will have such a condition that 50% of the worlds population will have insulin dependent Diabetes. Major reason for such a drastic increase in diabetic patients is the current life style, which nobody is willing to change. Thus we can say that in future recombinant Insulin will be highly demanded drug.

Work was done by carrying out a personal interview using a predesigned questionnaire. Mainly Diabetes specialists were interviewed. Interview was based on questions related various manufacturers of insulin, technology employed for manufacturing, cost of various insulin formulations and factor affecting cost of the product.

After analyzing the data graphically and statistically we came to see that 70% respondents claim that it is hard to have drastic decrease in the cost of recombinant human Insulin as India is lacking its own technology and infrastructure. 73% respondents agree that to fight with the war against diabetes, decrease in the cost is the ultimate requirement. There was 93% support about the fact that without involvement of government it is not possible to have low cost Insulin.

Real tumbling of prices can be expected when human insulin produced by Indian pharmaceuticals

actually hit the market. In future an additional survey regarding various manufacturing factors that will affect the cost should be carried out by consulting various insulin manufacturers.

HP 13 Evaluation of antidepressant and antistress activity of *Cystisus scoparius Link* and *Andrographis paniculata* Nees in Wistar Rats

Nirmal J*, Saravana Babu C, Harisudan T, Jayadev S, Ramanathan M and Suresh B.

J.S.S College of Pharmacy, Rocklands, PB. NO:20, Ootacamund - 643001, Tamil Nadu.

The present study was planned to evaluate the antidepressant effect of *Cystisus scoparius* Link and *Andrographis paniculata* Ness in mild chronic unpredictable stress induced depression. The depression was induced by following the method of Pal and Dandya. The antidepressant effect of the herbs was evaluated by using behavioural despair test and locomotor activity evaluation, the data were also supported by biochemical measurements. The *Cystisus scoparius* Link and *Andrographis paniculata* Ness were air dried and extracted with 60% methanol followed by vacuum drying and kept in the desicator. *Cystisus scoparius* and *Andrographis paniculata* were standardized to its phenolic content using Follin-Ciocalteau method and the percentage was found to be 3.64±0.16 and 8.54±0.16 respectively. Twenty one days administration of stress resulted in depression as indicated by decreased body weight, aggressive behaviour and increased immobility period in Porsolt's swim test. Blood glucose, protein level and ulcer scores were also found to be altered with stress. Treatment of *Cystisus scoparius* (250mg/kg) and *Andrographis paniculata* (200mg/kg) standardized methanolic extract significantly reversed the stressed induced depression. In comparison to *Andrographis paniculata, Cystisus scoparius* produced significantly better anti-depressant activity. It can be concluded that standardized *Cystisus scoparius* and *Andrographis paniculata* have antidepressant property.

HP 14 *In vitro* evaluation of hepatoprotective activity of *Caesalpinia sappan* in the freshly isolated rat hepatocytes

P.Vijayan, S.A.Dhanaraj, N.Hari, V.S. Srilakshmi, P. Vasanth Raj*, and B.Suresh.

Department of Pharmaceutical Biotechnology, J.S.S. College of Pharmacy, Rocklands, Ooty.

Caesalpinia sappan Linn. (Caesalpiniaceae) is a small thorny tree, 6-9 meters high. It is known to posses anticonvulsant, anti-inflammatory, anti-proliferative and vasorelaxing activity. Except this so far investigation of Hepatoprotective activity of this plant has not been carried out.

In this study we report the activity of aqueous and methanolic extract of heartwood of *Caesalpinia sappan* in CCl_4 induced toxicity in freshly isolated rat hepatocytes. The aqueous and methanolic extract were taken and dissolved in DMSO and made upto 10ml. with F12 Coon's/MEM to obtain a stock solution of 1mg/ml concentration and stored at -20°C prior to use. Further dilutions were made to obtain different concentrations ranging from 100-800µg/ml with respective media and used for in vitro investigations.

The Hepatocytes were isolated and cultured in Ham's F12 medium. Isolated hepatocytes challenged with CCl_4 (1%) were exposed to different concentration of extracts and incubated for 1 hour at 37°C. Effect of extracts on the biochemical parameters Viz., ASAT,ALAT, ALP,TGL, Total protein, Albumin, Total Bilurubin, Direct Bilurubin, Cholesterol were recorded. The aqueous extract of *Caesalpinia sappan* was found to be better in exhibiting the hepatoprotective property than the methanolic extract.

The aqueous extract showed that at the concentration of 1000µg/ml was able to restore all the biochemical parameters tested except for TGL and Cholesterol levels restore to normal with the concentration of 500µg/ml extract itself. The restoration level of enzymes for aqueous extract was found to be Albumin-200µg/ml, TGL-400µg/ml, Total protein-300µg/ml, and ALP-200µg/ml.

HP 15 Free radical scavenging studies of *Grewia tiliaefolia*

S.A.Dhanaraj, P.Vijayan, Samir Phulari*, K.Swapnil, Yadav Vivek, and B.Suresh

Department of Pharmaceutical Biotechnology, J.S.S.College of Pharmacy, Rocklands, Ooty.

Free radicals have been implicated in a variety of conditions including inflammation, atherosclerosis, diabetes, ageing and hepatic toxicities. Oxidations of free radicals are prevented by antioxidants. The antioxidants are available as synthetic and natural. The natural sources is more safety compared synthetic antioxidants.

The shade dried powdered leaves, barks, and flowers were exhaustively extracted with methanol (95% v/v) using a Soxhlet apparatus. The total methanolic extract was concentrated to a syrupy consistency.

The free radical scavenging was done by 1,1-diphenyl-2-picryl hydrazine (DPPH) method. The methanolic fractions of *Grewia tiliaefolia (Tiliaceae)* leaves, barks, flowers were studied for its antioxidant

property at different concentrations ranging from a maximum 1000µg/ml to a minimum 15.625µg/ml. The experiment was done in microtitre plate. 200µl of ethanolic solution of 0.05mM DPPH was added to 10µl test sample. Methanol was used as standard. After 20 minutes, absorbance was recorded at 517 nm. The five concordant values were taken and average was calculated. The percentage scavenging was calculated using the formula : (Standard - Sample) / Standard x 100.

It was concluded that, the three extracts of *Grewia tiliaefolia* have good free radical scavenging property. The IC_{50} values of barks, leaves and flowers were found to be 15.656µg, 40.875µg. and 99.436µg respectively. The plant barks showed very good antioxidant activity when compared to leaves and flowers, but the later also proved the good antioxidant activity in low concentration.

HP$_{16}$ Cytotoxic Investigation of *Lantana camara* Linn. using animal cell culture

Raghu C, Vijayan P, Ashok G, Sreenivasulu L*, Dhanaraj S.A, and Suresh B.

Department of Pharmaceutical Biotechnology, J.S.S. College of Pharmacy, Rocklands, Ootacamund 643 001.

Lantana camara Linn. is a large evergreen strong smelling herb, native of topical America, but now naturalized in many parts of India. All the parts of this plant are being used traditionally for several ailments throughout the world. Methanolic extracts of different parts of the plant *Lantana Camara* were prepared by single soxhlet extraction using methanol and screened for cyrotoxicity against HEp-2. $B_{16}F_{10}$. A-549 and NRK-49F cell lines using standard MTT and SRB assays. All the extracts were also screened for short term toxicity studies using DLA Cells. The leaves extract showed moderate cytotoxic activity against all the five cell lines tested. The human small cell lung carcinoma cell line. A-549 was found to be more susceptible to extract with a CTC_{30} value of 48.14 to 58.48 µg/ml. All the other extracts showed less activity. In short term toxicity studies, the methanolic extracts of the root and leaves showed moderate activity against DLA Cells. The study shows the moderate cytotoxic activity of *Lantana Camara.*

HP$_{17}$ Stabilization of secondary structure of Lasota vaccine during lyophilization

S S Pisal, J J Mane*, M H Shah, S S Kadam

Dept. of Pharmaceutics, Bharati Vidyapeeth Deemed University, Poona College of Pharmacy, Pune-411 038

The research was aimed to minimize product defects and lyophilization induced denaturation of lasota vaccine. Although coherent cake was observed with PF127 and PVP K-90, single components including sucrose and trehalose show poor protection of antigen. N, Z amine produces friable plug with sucrose and nonhomogenous Maillard cake browning with trehalose. Product shrinkage in PF127 plugs and granular cake showing irregular air spaces in PEG 6000 plugs were noted. Lowest residual moisture in PF127 and PVP K-90 is attributed to porous cake structure. Sugars alone are inadequate in building uniform cake and with non-polymer excipients retain moisture. DSC curves reveals endothermic melting corresponding to partial crystallization of PEG 6000 and PF127, while remaining plugs were amorphous. Diffused maxima in 16 -26^0 (2è) with PVP K-90 and N, Z-amine batches and crystalline peaks of PEG 6000 and PF127 in XRPD confirms the DSC findings. Aqueous IR of harvest reveals symmetrical alpha helix (1654 cm^{-1}) of antigen. Loss of alpha helix in lasota formulations is indicated by the decreased absorbance of 1654 cm^{-1} band, compensated by increased absorbance in beta sheet, turns and bends. The qualitative comparisons of alpha helix region in aqueous IR spectra are in correlation with antibody titer. Trehalose with most excipients gives better titer than sucrose. The stable glass matrix with arrested molecular mobility prevents unfolding of lasota. PF127 is better stabilizer than PEG 6000, but both crystallize during freezing. Trehalse-PVP K-90 shows optimum product characteristics and maximum protection to antigen.

HP$_{18}$ Strain improvement and increasing proteolytic activity of soil isolated strain of actinomycetes UVS-178 G.

S.A.Dhanaraj, P.Vijayan, T.S.Shanmugarajan, B.Sathesh*, and B.Suresh

Department of Pharmaceutical Biotechnology, J.S.S. College of Pharmacy, Rocklands, Ooty. Tamilnadu - 643001.

Proteases are the most important industrial enzymes accounting for about 60% of the total enzyme market and have number of application in industries and pharmaceuticals. The nine strain of Actinomycetes isolated from the soil and biochemical tests were performed, S-17 was found to be a good producer of extra cellular protease enzyme. Protease production was better in Reese's medium containing 0.5% of casein, 0.25% of dextrose.

The enzyme activity was increased by strain improvement technique, the isolated strain was mutated by UV irradiation. More activity was identified with the mutated strain named as UVS-178G. It showed 1.4cm more zone of clearance than isolated strain in milk agar medium. The enzyme assay was done by UV absorbance method at 280 nm as per modified Lowry's method.

The mutated strain enzyme production was further increased by medium optimization. Maximum enzyme production was obtained 0.50 % casein and 0.50 % dextrose concentration. The strain improved Actinomycetes were fermented with help of Fully automated Laboratory fermentor and the protease was isolated from the culture filtrate of UVS-178G by ammonium sulphate precipitation .It was purified by dialysis and enzyme activity were determined by modified Lowry's Method.

HP 19 Applications of bioinformatics in pharmacy field

Pawan Gupta*, Vijender S. Shekhawat, R. K. Nema, Dheeraj K. Gupta, Santosh Gupta

Subhash Nagar, Udaipur, Rajasthan

Bioinformatics played a decisive role in the most prominent scientific achievements during recent years, the sequencing of the human genome. With the sequence being known, the annotation of the genome can begin. This means searching for the gene DNA, identifying the corresponding gene products (proteins, RNA), as well as explaining their function and structure. In order to fully understand protein function one has to consider their interplay. These interactions are represented by metabolic and regulatory network, which, among other things, can be simulated using computational methods. Antibiotic resistance amongst virulent species is on the increase, causing major concern worldwide.

It is evident that some current therapies are no longer effective, and accordingly, novel Antimicrobials will need to be developed. To help counteract these problems, advances in technology can be used to hasten the hunt for new drug and vaccine targets. One obvious advantage of using computer- based screening techniques (Bioinformatics) to scan newly sequenced pathogen genomes is the speed at which identification of novel targets can be carried out.

Bioinformatics supports the optimization of known therapies. The comparison of complete genomes of different individuals makes it possible to trace differences (SNP^s), which may play a role when deciding on the individual therapy for a patient. In general, drugs act by influencing the proteins that are involved in metabolism. Based on the assembly of the human genome Bioinformatics methods allow researchers to find proteins (Targets) that are better suited for treating certain diseases. Those most relevant to Bioinformatics are Biochemistry and Molecular Biology, Ecology Evolution and Systematics, Plant Sciences, Neurosciences, Computer Science and Technology.

The publication of the human genome sequence in February 2001 is considered to be a milestone of scientific research. This is reflected in the reaction of the media and the public. Bioinformatics tools are quintessential for this achievement.

HP 20 Serum antibacterial assay and pharmacokinetic Interaction study of ofloxacin in the presence of multivitamins and probenecid respectively in healthy human volunteers

C. Sundaramoorthi*[1], K.L. Senthil Kumar[1], T.K. Ravi[2], S. Krishnan[2]

1. Padmavathi College of Pharmacy, Dharmapuri, TN. 635205.
2. College of Pharmacy, Sri Ramakrishna Institute of paramedical sciences, Coimbatore - 641 044.

Most drug interactions are special kind of adverse drug reactions in which the effects of a drug are altered by the effects of another drug. In a few cases such an interaction may prove beneficial.

Drug interactions involve one drug which precipitates the change in effects of another. Occasionally in an interaction the effects of both may be altered. The microbiological assay for ofloxacin developed in our study has been used to check for any interaction likely, when ofloxacin may be combined with multivitamins and probenecid. The possibility of such a combination being used is very much likely (both clinically on prescription or as self medication) and hence the clinical significance of such a combination was taken up as part of our work.

Here the organism tested is exposed to a diffusion gradient of the antibiotic contained in a disc of filter paper or filled in cups bored on the surfaced of the nutrient agar in petridishes. The formation of inhibition zones represent the dynamic interaction between antibiotic diffusion and bacterial growth. The zone of inhibition measured (mm) reflects the degree of susceptibility of resistance of microorganisms towards the antibiotic.

Our results suggest that the ofloxacin multivitamins combination resulted decrease in ofloxacin levels (n=3) and ofloxacin - probenecid combination resulted slight increase in ofloxacin levels when given concurrently (n=3) observed.

IP$_1$ A critical study analysing the drug-use practices of nurses with reference to WHO-INRGUD guidelines

S. B. Bhise [1], Abhijit D. Nalawade*[2]

1. Principal, Govt.College of Pharmacy,Aurangabad.
2. Govt. College of Pharmacy ,Karad-415 124.

Nurses in Primary Health Centres (PHCs) and their sub-centres comprise a sizeable group administering medicines. Nurses stationed in (PHCs) use medicines mostly under the supervision of the Medical Officer; whereas nurses in sub-centres have to use them generally without any direct supervision of doctors because Medical Officers visit sub-centres only on specified days, so it is necessary to know whether the PHC nurses know enough about the medicines which they give to patients on their own. A study was conducted as per guidelines of WHO-INRUD (World Health Organisation-International Network for Rational Use of Drugs.)

A survey was conducted in Hingoli District of Maharashtra by selecting 24 health centres-14 PHCs along with 1 or 2 sub-centres attached to each of these PHCs and their distribution was as per backward, average and developed zone. The list of medicines included in the sub-centre kit contains 10 medicines for which 24 nurses were assessed by administering a questionnaire. Analysis of questionnaire was done by giving marks to different sub-components of the answers. The average score per drug was 287 out of 576(49.9%) and also for knowledge about indications, precautions and dose per drug was 68.17%, 28.96% and 75.19% respectively.

In conclusion we can say that the knowledge of 24 PHC nurses about the common drugs their indication and dosage was satisfactory, but was quite unsatisfactory about precautions to be given to avoid side effects.

IP$_2$ A study on drug compliance response of patients in an out-patient department of satara district, Maharashtra

S.B.Bhise[1], Arundhati D.Nalawade [2],Vikas R.More[3], Abhijit D.Nalawade *[4]

1. Principal, Govt.College of Pharmacy,Aurangabad.
2. Aryangla Hospital, Satara - 415 002.
3. Pharmacist, Jehangir Hospital, Pune.
4. Govt. College of Pharmacy, Karad-415 124.

The load of illness in a developing nation like India, is enormous. Morbidity and mortality can be reduced markedly by the patients compliance to their prescribed regimen of drugs. This practice, however, varies from non-compliance to complete compliance through various degrees of partial compliance.

The study was carried out amongst persons residing in and around of the Outpatient Department (OPD) of Aryangla Hospital, Satara. During the study period a total of 264 OPD cases were included. Compliance to medical regimen was based on acceptance of essential drugs prescribed to the patient with reference to his/her illness.

The proportion of fully compliant, partially compliant and non- compliant was 58.9%, 40.1 %, and 0.8% respectively . Reasons of compliance failure at every follow-up were identified in those groups where partial and non-compliance were observed. The first five reasons were side effects of drugs (29.0%), forgetting the dose (21.7%), bad taste of drug (14.0%), no benefits from drugs (7.3%) and social reasons (5.1%).

It may be concluded that the fully compliant patient had understood the prescription properly, was prescribed less number of drugs, thought the treatment to be effective, could identify the drug prescribed, had a good impression of the treating doctor's acumen, behavior, way of examination and explanation of the disease.

IP$_3$ Study of morbidity of children under 5 years in a slums area at Berhampur

P. K. Panda, S. N. Das, D. Pradhan

U.D.P.S. Utkal University, Bhubaneswar.

Diseases are as old as living being came to existence in the world. The pattern & severity of diseases are becoming day by day very critical. The diseases like respiratory illness, infective diseases & other communicable diseases if they are left untreated may lead towards mortality. The children are the future of the Nation & if he is deprived of health care, then his future will be in dark.

A study of morbidity among the children under 5 years have been conducted in a slum area of Berhampur in Ganjam district of Orissa. Total 1040 children were examined for different types of morbidity condition they possessed. It is found that 293 out of 1040, children (28.1%) of children had shown respiratory illness, 97 children out of 1040 children (9.32%) were suffering from diarrhoea. 39 children that is (3.75%) of children were suffering from skin diseases. 90 (8.65%) of children were suffering from vitamin B complex deficiency diseases. 312 (30%) of the children were suffering from malnutrition. The rest of the children are showing the morbidity conditions like vitamin A deficiency, dentalcaris, conjunctivitis, prolapsed rectum, lymphadenitis etc.

IP4 Impact of trade name on sales and promotion to self medication

M.B. Patel*, M.M. Patel, C.N. Patel, J.R.Patel, P.D. Bharadia, B.N. Suhaghia

Shree S.K. Patel College of Pharmaceutical Education & Research, Ganpat Vidyanagar, Kherva, Dist: Mehsana, Gujarat. 382711

In recent years numbers of drug formulations have been increasing in Indian market under the names like Dimpy, Don, Pan, Pentium, Pentin, Acrobet, Yahoo, XL-90, Cibar-CT, E-Mail, Nice, etc.

The aim of present prospective randomized control study is to co-relate the effect of drug's trade name on self-medication and sales promotion.

The study was carried out on effect of trade names of several medical products on self-medication through a well-designed questionnaire to patients, community pharmacist and doctors. Survey was undertaken over three districts of Gujarat. The questionnaire was systematically and scientifically documented and analysed.

As per data collected 200 brands were found to be used regularly in self-medication and their continuity was more than 8 months to one year. The measure reason is due to pet names only.

15 brands were found to contain changed therapeutic ingredients with similar misleading earlier brands name like dispirin-plus, which contain paracetamol instead of aspirin, which was being used by cardiac patients.

23 brands were intensely substituted by pharmacist on counter practice like penagra, giagra for viagra.

The study clearly indicated that pet names create direct professional linkage between the products (company) and patients and by giving simple pet names, number of patients could be increased for self-medication. The findings reflects that effect of pet names of drug increased 69% self-medication, 16.8% substitution by retail outlet and 14.2% through recommendation of patients to patients.

There is an urgent need to address this issue by the drug control authority and concrete measures should be taken to stop misuse of such products.

IP5 Preliminary survey on prescription patterns and knowledge adequacy of thyroid patients

Kumar Sanjeev, Singh Shashank, Valecha Varsha Garg Arun, Agrawal S.S.

College of Pharmacy, Pushp Vihar, Sector 3, New Delhi 17.

The two most important thyroid hormones are thyroxine (T4) and triiodothyronine (T3) representing 99.9% and 0.1% of thyroid hormones respectively. The hormone with the most biological activity is actually T3. Thyroid Hormones stimulate enzymes that combine oxygen and glucose, a process that increase the basal metabolic rate (BMR) and body heat production. They also help maintain blood pressure, regulates tissue growth and development, is critical for skeletal and nervous system development and plays an important role in the development of the reproductive system. The thyroid gland can malfunction in one of the three ways. It can release too little TH, resulting in a condition known as hypothyroidism (under active thyroid). It can release too much TH, resulting in a condition known as hyperthyroidism (overactive thyroid). Its tissue can overgrow, resulting in a nodule, a small lump in part of the gland. Most nodules are harmless growths, but a small percentage are cancerous \Thyroid diseases, generally more common in females than males includes hypothyroidism, hyperthyroidism, euthyroid sick syndrome, multi nodular goiter, thyroid cancer, etc. A prospective study was conducted on thirty patients of INMAS (Institute of Nuclear Medicine and Allied Sciences), Delhi. The study concluded that the thyroid disease is more common in females (86.6%) than in males. The disease was found to be more common in middle age group 30-50 years. Body Weight was markedly increased in patients with hypothyroidism and it showed a drastic decrease in hyperthyroid patients. The presence of family history was reported in 30% of the patients surveyed . The drugs mainly prescribed were ELTROXIN (l- thyroxin) for hypothyroid patients and NEOMERCAZOLE for hyperthyroid patients. Surgery (thyroidectomy) was recommended only to 10% of the patients. Only 13.33% of the patients were illiterate and about 33.3% had done schooling. Others were Graduate and post graduate. 73.3% of the patients had inadequate knowledge about the disease so there is an urgent need to develop a program for the education of the patients about the Disease. Correlation between education level and knowledge shows that the high education level of the patients surveyed, most of them were not having adequate knowledge about the disease. The commonest symptoms experienced were dyspnoea, weight gain (hypothyroidism), weight loss (hyperthyroidism), palpitation, exophthalamos etc. Recommendation of surgery - Only 10% of the patients were recommended for surgery. Most of them had mild to moderate disease. Radioactive iodine (RAI) administration was done only to patient out of the thirty patients surveyed.

IP6 Drug utilization study in paediatrics out patient setting at a Private medical college hospital.

Philip Jacob*, B. Arul, B. Sangameswaran and B. Jayakar

Vinayaka Mission's College of Pharmacy, Yercaud main Road, Salem - 636 008, Tamilnadu.

The present study was designed to assess drug utilization in Paediatrics out patient at a private medical college hospital. A study was undertaken for 2 months (June - July 2003). Prescriptions were copied after the consultation of the patient with doctor.

A total of 402 prescriptions were collected and from that 45.02% were males and 54.98% females. 88.05% of patients received 5 drugs or more. 77.11% received injections. An average consulting time was less than 5 minutes. 52.73% patients received antibiotics. Amoxycillin was most commonly prescribed antibiotic. Irrational use of drugs causes many problems including inappropriate treatment, iatrogenic diseases, the growth of resistance and a huge waste of resources. From this study it revealed that the incidence of Polypharmacy, excessive prescribing and irrational use of drugs.

IP$_7$ Practice of rational drug use in accordance with WHO guidelines

Deeshant Shah Patel*, K. Reeba Varghese, Raman Dang

Al-ameen College of Pharmacy, Hosur Road, Near Lalbagh Main Gate, Bangalore 560 027

According to WHO, RATIONAL DRUG USE is when "patient receive medications appropriate to clinical needs, in doses that meets their own requirements, for an adequate period of time, and at the lowest cost to them and their community".

Various case studies were studied and conclusions were drawn. Expert opinions, questionnaires, internet, surveys helped discussions and suggest views on this critical and crucial topic.

An indicator study completed in Kalahari district of Northern Cape, illustrated that, Kwik-Skwiz deals with the measurement of drug use pattern and prescribing behaviour and also with the structures which can be used to promote rational drug use at district levels.

Patients using oral NSAIDs who suffered from acute gastrointestinal bleeding knew less about their drugs side effects or what to do if they occur than more informed patients using the same drugs.

The boundaries between different health professions have been blurring over time. The process of prescribing is complex. It has been described as involving patient assessment, investigations, diagnosis and follow up. In addition to drug selection, monitoring and adjusting drug treatment.

The increasing number of people allowed to prescribe might be that nurses or other health workers like a Pharmacist prescribe cheaper and fewer drugs than medical practitioners achieving the same results. There is a considerable scope for the improvement in the quality of prescribing primary care level.

Development and implementation of National Drug Policies are carried out within the overall National Health Policy context with case taken to ensure that their goals are consistent. Certain strategies can be adopted to promote RATIONAL DRUG USE.

IP$_8$ Extensive adverse drug reaction (ADR) casestudies, implications and solutions

Deeshant Shah Patel*, K. Reeba Varghese, Raman Dang

Al-ameen College of Pharmacy, Hosur Road, Near Lalbagh Main Gate, Bangalore 560 027

An ADVERSE DRUG REACTION is an untoward reaction associated with drug use. ADRs are very common and most are preventable through careful and thorough management.

Recent cases were selected based on their serious frequency of occurrence or the fact that reactions are unexpected,

The Canadian product monograph for Glatifloxacin was recently updated in response to reported cases of serious life threatening disturbances of glucose homeostasis.

A 62-year old woman sued her physician for evaluation of toe-nails that had thickened and were tendered on ambulation.She was treated with 400mg of itraconazole per day but on third day of this therapy;nausea,anorexia and lethargy was developed.It was an ADR due to itraconazole.

A proven cause and effect relationship between the reaction and suspected drug(s) is not required before a reaction is reportable; reasonable suspicion is sufficient. Blood products should be specifically excluded from adverse drug effect monitoring and should be reported utilising reporting mechanisms specifically designing for these products.

An ADR may result from the administration of OTC, prescription,or investigational/research drugs.It includes adverse events occurring from drug overdose, whether accidental or incidental

There are lot of drug reactions occurring all over the world. When a reaction is identified to a drug that has been on the market for years and has thousands of users, the news often make the headlines leading to confusion and fear.

IP$_9$ A comprehensive study of disease and prescription pattern in respiratory tract infection (RTI) in the newly formed state of Jharkhand

Avijit Mazumder, Sangita Kumari*, Rupa Mazumder**

Department of Pharmaceutical Sciences, BIT Mesra, Ranchi - 835 215.

Respiratory Tract Infections (RTI) is found to be one of the most common infections prevailing in different parts of Jharkhand. It was found from a survey conducted in different parts of the state with a set of structured questionnaires framed after a pilot study targeted at patients and doctors, that this disease was more prevalent among males (72.2%) particularly belonging to the age group of 40 to 60 years. Children below 10 years are found to be more susceptible to RTI. The poor tribals of the rural areas were suffering more from RTI than the urban people. This may be due to poverty and illiteracy. Smoking, improper health and hygiene including improper sanitation random uses of drugs are some of the factors leading to the widespread occurrence of this disease of the state. Cough, breathlessness, chest cold, rhinitis and fever were the major complaints of the patients. *Klebstella Pneumoniae* (28.7%) was mostly found to cause RTI followed by *Streptococcus pneumoniae* (25%). *E. cold* (21.5%). *Pseudomonas derugmosa* (15.2%) and *Staphylococcus amreus* (8.4%). The reports of RTI caused by *Streptococcus* and *Pseudomonas* spp. have increase in the last few months Ciprofloxacin and Ofloxacin were found to be prescribed in maximum number of patients followed by Amoxycillin and Chloramphenicol. Patients on combination therapy had much better control of this disease. The random use of antibiotics without prior consultation with doctors have resulted in generation of resistant pathogenic microorganisms making the control of this disease very difficult. So avoidance of smoking, random use of antibiotics and maintenance of proper health and hygiene can help to control the occurrence of RTI in the state of Jharkhand.

IP$_{10}$ Patient information leaflets for enalapril and metronidazole - patient's perspective

Manjiri Gharat*, Jay Visaria, Dr. Rajani Shettigar, S. S. Poddar

K M Kundanani College of Pharmacy, Worli, Mumbai

Patient information leaflets (PILs) offer a tool for providing patient education, to improve patient compliance and heighten the patient's involvement in therapy.

To evaluate patient's opinion on the potential use of Patient information leaflets (PILs) using sample PILs for two representative drugs.

Part A - Sample PILs for two representative drugs viz. Enalapril and Metronidazole were prepared using the standard drug information sources and as per the prescribed guidelines.

Part B - PILs were distributed to patients (n=50) in Mumbai, for whom the representative drugs were prescribed. Feedback was collected using close-ended objective type questionnaire and suitably analyzed.

80% respondents had received written information about diseases and drugs in the past - familiarity of the concept.

66% respondents wanted the PIL in English; the language associated with most drug information. There was also significant demand for PILs in local languages.

Over 90% respondents were satisfied with the information given regarding indications and method of taking the drug.

Over 80% respondents felt that the PILs were easier to understand than both, verbal information and the manufacturer's package insert (if at all present).

92% respondents wished to regularly receive PILs, especially drugs requiring long-term use. Patients wanted shorter PILs without pictograms or graphics, which may have potentially ambiguous meanings. Only 60% were clear about dosage schedules and drug-food interactions - indicating need for further refinement

PILs were well received by the patients and show good potential in improving safety and efficacy of drug therapy.

IP$_{11}$ Fighting HIV / Aids : Is Success Possible?

S.B. Bhise, Santosh R. Tarke Matin Y. Bagwan, Shridhar R. Mangnalikar & Umesh S. Jadhav*

Govt. College of Pharmacy, Karad, District - Satara.

Acquired immunodeficiency syndrome (AIDS) was described in June 1981, and has subsequently become the most important infectious disease being the 4th leading cause of death worldwide. More than 15,000 people are infected with HIV everyday 95% of which live in developing countries.

This article gives the detail report of AIDS patients reported in Civil Hospital at Satara & Sangli Dist. of Maharashtra State, India. The total No. of AIDS patients were found to be 578 in the year 2002-2003.

The data was analyzed on the basis of Age, Sex, Route of transmission. 381 male (65.9%) & 199 (34.42%) female were found to be HIV positive in a population study of 578. Among these, 245 (42.38%) patients belong to age group 20-29. Patients in age group 40-49 are 92 (15.9%), & No. of perinatal patients reported were 30 (5%).

Most of the patients are infected by HIV, through sexual route of transmission (62.28%) & by blood & blood products (3.14%).

The percentage of opportunistic infection associated with AIDS patients are, TB (67.9%). Candiadiasis (21.74%), Herpes & Meningitis (0.69) & cryptosporidium (1.2%). These patients are also found to suffer form various other symptoms like weight loss, asthenia, fatigue & low grade fever.

The outcome of the study is to understand the magnitude of AIDS, plan & evaluate control strategies effectively for prevention of AIDS. The most effective approach to prevent HIV infection is to induce behavioral changes, prevention of co-factors STIs & the existing infrastructure for public health service. The study concludes that HIV / AIDS poses enormous challenges, generating fear that success may be too difficult or even impossible to attain.

IP$_{12}$ Survey of national leprosy eradication programme (NLEP), in District Satara

S.B. Bhise, Santosh R. Tarke, Matin Y. Bagwan, Shridhar R. Mannalikar* & Pravin Kamble

Govt. College of Pharmacy, Karad.

Leprosy or Hansen's disease - A chronic infectious disease is more prevalent among developing countries. According to WHO - India contributes 1/3rd of world leprosy patients. Hence government has undertaken National Leprosy Eradication Programme (NLEP) with a goal to eradicate leprosy by 2005.

An extensive study was conducted from April 2002 - March 2003 in Satara District of Maharashtra State through periodic visits at District Civil Hospital and 71 Primary Health Centre (PHC) for leprosy cases. The study was focussed in urban and rural area and collected data was analyzed based on type of disease - Multibacillar (MB) or Paucibacillary (PB), Sex, Prevalence rate (PR), New case detection rate (NCDR) and Deformity percentage.

The study highlighted following aspects -

A. Urban Area

- Among 3,52,568 urban population 355 leprosy cases were registered.
- 154 cases were positive for Multibacillary and 201 for Paucibacillary.
- The male percentage in total cases is 56.33% and that of female 43.66%.
- The children percentage was 18.39%.
- The Deformity percentage was 0.28%.
- NCDR 0.82/1000 cases.

B. Rural Area

- 898 Leprosy cases were found 25,80,383 Rural population.
- Multibacillary - 321 Paucibacillary - 577.
- Male percentage was 58.79%; Female percentage was 35.74%.
- Children percentage - 17%.
- No deformed cases were reported.

The results reflect the prevalence rate and NCDR/1000 population is more in rural area than urban. This is indicative of poor socioeconomic conditions, unhygienic conditions, poor sanitation and lack of awareness about leprosy in rural areas.

IP$_{13}$ Dots : Break through to Tuberculosis (TB)

S.B. Bhise, Santosh R. Tarke, Matin. Y. Bagwan, Shridhar R. Mangnalikar* Umesh Jadhav

Govt. College of Pharmacy, Karad, District - Satara.

Tuberculosis (TB) has already infected 1/3rd of the world's population. The mortality rate of TB is 1000 per day with one death per minute in India.

This article present the result of a study to determine the true outcome of treatment received by pulmonary TB and Extrapulmonary TB patients registered during Jan 2002 to June 2003 under RNTCP in Satara & Sangli district of Maharashtra, India. The treatment outcomes were collected from respective District TB centre. The patients (n = 8707) are given treatment in category I (n = 4213), category II (n = 1446) and category III (n = 3048).

True outcome of treatment of total patients is categorized as:

- Patients with smear negative reports after treatment (i.e. Cure Rate)
- 82.49%.
- Patients died during the treatment (Death Rate) 7.25%.
- Patients did not collect their drug for two consecutive months
- (Default Rate) 3.87%.
- Patients with smear positive after completion of treatment (Failure Rate)
- 5.33%.
- Patients cured plus those completing treatment and are clinically well
- (Success Rate) 83.39%

- Patients whose sputum reports converts from positive to sputum negative
- (Conversion Rate) 86.71%.
- New sputum positive detection rate 42.63%.

DOTS is symbolized by the outstretched hand of the health worker who provides powerful Anti-TB medicines to patients and monitors the therapy. Because of the DOTS strategy, we now have the means of preventing up to 50 million death from TB in the next few decades. For the first time, we have a winning hand to defeat TB in developed and developing countries alike.

IP14 Tobacco use in urban and rural areas of karad, Satara District

S.B. Bhise, Santosh R. Tarke, Matin. Y. Bagwan, Shridhar R. Mannalikar* & Sushil Sarvagod

Govt. College of Pharmacy, Karad.

In India almost every second adult has tobacco dependence, every 5th child starts experimenting with tobacco and every 10th child is hooked on tobacco. Tobacco is measure cause of preventable mortality.

The objective of this survey is to assess tobacco use, awareness and attitude towards tobacco and smoking in rural area and college students of Karad, District Satara, Maharashtra.

The data was collected by circulating questionnaire in local language among 1250 people, 750 from rural and 500 college students and analyzed on,

- Sociodemographic status.
- Passive and active tobacco use.
- Awareness and attitudes towards tobacco consumption.

34% Rural Population and 65% college students consumed tobacco and related products. In rural area traditional tobacco consumers were 51.76%, Bidi 26.24%, Cigarette 15.72%, Mishari 7.87% and snuff 4.8%.

In rural area, consumption of tobacco and related products is 9.8% in age group 18-25:, 18.82% in age group 25-34, 21.95% in age group 35-44 & 30.27% in age group 55+. The consumption of tobacco and related products in male is 26% and 8.1% in female.

In survey of 500 college students, distinction was made to facilitate data analysis as, who never smoked 35.5%, occasional smokers 7.4%, experimental smokers 40.4%, Ex-smokers 3.5% and regular smokers 13.2%.

The people of rural area are not much aware of the diseases related to tobacco and smoking. The percentage awareness among the people is only 20% while that in college students is 65%.

Informational and educational campaign relating to tobacco control should be directed at individual and communities taking into account the gaps in awareness of the effects of tobacco on health.

IP15 Potential drug-drug interactions in the medications of inpatients at a public teaching hospital

***Pawar Shrikrishna B.[1], Tiwari P[1], Agarwal Vikas[2]**

1. Department of Pharmacy Practice, National Institute of Pharmaceutical Education & Research, S.A.S.Nagar, Punjab
2. Department of Medicine, Government Medical College & Hospital, Chandigarh

Polypharmacy, the use of two or more medications by one patient, has become prevalent in today's practice. Use of herbals and alternative medicines without the knowledge of the clinician increases chances of interactions. It is reported that approximately 37-60% of patients admitted to the hospital may have one or more potentially interacting drug- drug interactions (DDI). This study aimed to find out the incidence and significance of potential DDIs using computerized database in inpatient prescriptions of a public teaching hospital.

All the prescriptions containing more than one drug were selected from the medicine ward of a public teaching hospital & reviewed. Fifty patients of either sex, over 18 yrs of age, were included in this study. Each prescription was examined for the number of possible interactions in the prescription using the drug database Micromedex (DRUG-REAX system) 2003. The database provided the information on potential clinical significance as well as severity (mild, moderate, minor) of potential DDI.

The patients (average age-45.6 yr) were prescribed a median of 7.7drugs. Of the fifty prescriptions selected for the study, each prescription contained atleast one DDI. Of the total 56 DDIs found, 34% were potentially minor, 53% were moderate and only 13 % were of major severity. It was observed that when the numbers of drugs prescribed were between 11-14, the average number of interaction was three. The major classes of drugs involved in DDIs were cardiovascular, antibacterial, vitamins, minerals and electrolytes and antiepileptic drugs

It was found that of all the drug interactions observed, only 13 % were of major severity. Cardiovascular and antibacterial drugs reported highest interactions. The incidence of finding a DDI was higher when the numbers of drugs prescribed were between 11-14. Integration of a drug interaction software may be very useful while dispensing multiple medications.

IP 16 Provision & evaluation of drug information services to general practitioners of Mysore city

Nilambari G. Naik*, G Parthasarathi and M Ramesh

Dept. of Pharmacy Practice, JSS Hospital, Ramnuja Road, Mysore - 04

A survey was conducted to identify the resources used for drug information by GPs and assess their perception of drug information centres (DIC). Survey revealed that there is lack of awareness about DICs and most widely utilised source of information by GPs was product information leaflets and medical representatives. GPs were willing to utilise the drug information services if made available to them. Thus, drug information services to general practitioners of Mysore city was provided by Department of Clincal Pharmacy, JSS Hospital, Mysore.

The drug information services to general practitioners were initiated from 1st of January 2003. Random samples of 60 GPs were selected from different localities of Mysore City. Awareness about drug information services among the GPs was created by posting them a handout and personal visits. GPs were briefed about the activities of the department and resources utilised to answer drug information enquiries. Different methods of campaigning were adopted to promote the services and encourage GPs to utilise the service. A total of 119 queries were received over a period of seven months. Majority of the queries were related to drug use in special population. Standard texts and references were the most utilised source for answering queries. Most of the enquiries were to update knowledge. The quality of drug information was appreciated by the GPs. Though services provided were under utilised it was well appreciated. There is a clear need for periodic, well researched unbiased information on drugs and therapeutics to GPs. This opens up an important avenue for well-trained pharmacists to offer drug information services to community doctors and provide the pharmacists with an opportunity to play an active role in improving patient care in the community.

IP 17 Variability of serum phenytoin concentrations in Indian epileptic patient population

P. Kishore*, J. Vidya Sagar and Devarakonda R. Krishna

DMCPK division, UCPSC Kakatiya University, Warangal, Andra Pradesh- 09

Due to varied Pharmacokinetics behaviour and inter individual variation of the phenytoin, phenobarbitone and carbamazepine, serum level monitoring is necessary optimize the drug therapy. The present study was designed to study the relationship between serum levels of phenytoin and different patient related factors like the dose administered the effect of age, control of seizures and the influence of phenobarbitone and carbamazpine co-treatment on the phenytoin concentration in Indian epileptic patient population.

Blood samples were collected from the selected patient group (126 patients) and analyzed using a sensitive HPLC method.

Result and Discussion of 111 patient receiving phenytoin as mono theraphy, complete seizure control could be achieved in 80 patients (mean serum concentration of 12.46 ±10.9 μg / ml). The relationship between dose and concentration of phenytoin is non linear as the concentration does not increase proportionally with the dose. Polytherapy had no additional benefit in controlling seizures. 74.5 % of the patients had seizures completely controlled with serum phenytoin level below therapeutic range. Higher doses were also well tolerate by Indian patients

The relationship between the phenytoin dose and concentration is not linear.

In the epileptic patients on monotherapy, the seizure control with phenytoin was observed in the concentration range of 3.9 to 29 μg / ml with a mean (± SD) of 11.56 ± μg /ml. Patients showing therapeutic benefit ranged with serum drug level from sub therapeutic level to toxic level indicating the reference theerapeutic range (10 to 20 μg /ml) has to redefined for Indian epileptic patient population.

IP 18 Study of polypharmacy prescription in Taluka Vyara, Dist-Surat, South Gujarat

Nancy A. Shah *, K.J.Gohil

Maliba Pharmacy College, Tarsadi, Dist-Surat.

With an increasing number of drugs available in the market and the complexity of drug action along with the need of multiple drug therapy, the drug-drug interactions are frequently encountered which may sometimes lead to loss of therapeutic activity or adverse effects that may prove fatal.

The reason behind doing the study of prescription for drug-drug interactions is to describe the role of pharmacist in pointing out to the physician of an inadvertent interaction in his prescription and create awareness amongst nursing & paramedical staff to maintain a complete & accurate record of patient's medication.

Over 120 prescriptions were studied from randomly selected patients in Vyara of age group 6-60 suffering from cough, hypertension, malaria, skin disease, left ventricular hypertrophy, glaucoma and sinus tachycardia.

Various drug interactions came into light which were the consequences of overlooking the precaution measures necessary to avoid drug interactions, at the

same time, patient counselling should be done and time of administration, frequency of dose and other safety measures must be kept in mind.

Many drug interactions can be avoided if adequate precautions are taken like proper monitoring of the treatment, patient counselling and be keen at the observations, which have to be supervised while taking the drug.

Emerging science like Pharmacogenomics which suggests the individualize dosing and formulating system would help in improving rational drug therapy by preventing drug-drug interactions and improving patient compliance.

IP19 A study of the factors affecting prescription in the pune region

S.L.Bodhankar[a] , S.V.Gandhi[b]*, N.S.Vyawahare[b], S.V.Bhandari[b].

a. BVP's Poona College of Pharmacy, Erandwane, Pune - 400038.

b. A.I.S.S.M.S. College of Pharmacy, Near R.T.O., Pune -400001.

A questionnaire survey was conducted amongst 600 allopathic doctors working in private and service sectors, asking them to tick option that they consider for prescription. Results were calculated using descriptive statistics.

Accordingly 40.00 %, 27.33 % and 22.00 % of doctors cited availability; brand and cost of the drug respectively as important factor, while 10.66 % of doctors considered place of O.P.D., available dosage forms, side effects, etc.

Patient related factors like feed back reports (9.66 %), patient's opinion (8.16 %) and patient's history (23.33 %) found to be considered by less number of doctors.

Availability, brand and cost of drug were the important factors for prescription followed by patients feed back reports, patients' opinion and patients' history. The study also suggested that maintenance and consideration of patients' history, patients' feed back reports could improve effectiveness of therapy.

IP20 High prevalence and ignorance about diabetes and its treatment in the North Gujarat

Deval Patel*, Jayshree Patel, Nimisha Kataria, Krupa Modi, N. J. Patel, J. L. Patel, R. K. Goyal°

Shree S. K. Patel College of Pharmacy Education and Research, Ganpat Vidyanagar, Kherva-382711, Mehsana.

°L. M. College of Pharmacy, Ahmedabad-380009.

A study was conducted to search for the prevalence of diabetes mellitus with other complications and its awareness in North Gujarat. The study was aimed to check drug utilization and to evaluate efficiency of drugs prescribed also. A questionairres was designed and during patient's consultation with the physician, details of the questionairres were collected randomly from rural and urban area of Palanpur city in North Gujarat region. 90 patients were approached for the details and the data were analysed statistically.

Prevalence of diabetes was more in males (68.9%) than the females (31.1%) in North Gujarat. Diabetic patients with NIDDM were significantly more than the IDDM type. Hypertension with past history or family history was commonly observed than other cardiovascular disorders in diabetic patients. Poly urea, headache, skin diseases and eye complications were observed in diabetic patients. Large number of patients were found with much sweet (54.5%) and oily food (32.2%) before diagnosis of diabetes but after diagnosis, the patients were found more conscious for the regular checkup and treatment. Sulphonylureas (66.7%) were commonly prescribed to diabetic patients with Biguanides (33.3%) and Thiglitazones (12%).

IP21 Effect of bronchodilators on respiratory function tests in asthmatic patients of North Gujarat

N. J. Patel*, M. M. Patel, J. L. Patel, R. K. Goyal°

Shree S. K. Patel College of Pharmacy Education and Research, Ganpat Vidyanagar, Kherva-382711, Mehsana.

°L. M. College of Pharmacy, Ahmedabad-380009.

In pharmacoepidemiological studies of respiratory disorders, prevalence of asthma was found to be higher in both rural (36.2%) and urban (41.4 %) population. In treatment of bronchial asthma commoner groups of drugs prescribed are anti-inflammatory agents and bronchodilators. As bronchodilators, specific b1 selective adrenergic drugs like salbutamol, terbutaline, salmeterol etc and xanthine alkaloids like theophylline and etophylline were found to be commonly prescribed. They are mainly used by oral or by inhalational route. It is not clear whether the use of bronchodilators is effective in improving respiratory functions unlike diseases like diabetes mellitus, hypertension, cardiac failure etc. Physicians rarely prescribe respiratory function tests before, during or after the diagnosis of the patient as bronchial asthmatic. We have evaluated the respiratory functions of the patient using peak flow meter. PEFR (Peak Expiratory Flow Rate) recorded with the help of peak flow meter before treatment and after a week treatment of asthmatic patients.

Bronchodilators were found to be prescribed in all asthmatic patients and some patients in other

respiratory disorders. Most commonly prescribed bronchodilators were B2-selective agonist or their combination with methyl xanthines. In some cases corticosteroids or inhalers were also found to be prescribed with oral bronchodilators. Peak expiratory flow rate was measured for the patients with bronchial asthma before and after treatment with bronchodilators. There was 67.1% increase in PEFR in male and 65.3% in increase in PEFR in female after treatment. There was more increase in PEFR in patients with less duration of asthma as compared to those who had asthma from longer duration. Change in PEFR was significantly less in female as compared to male of the same duration of asthma. Improvement of PEFR was found to be similar irrespective of whether the bronchodilator is taken systematically or by inhalation. Our data suggest that improvement of PEFR was similar whether the bronchodilator is taken systematically or by inhalation. Therefore one can recommend use of inhalational bronchodilator to avoid adverse effects. Monitoring of respiratory function may be useful in better and cost effective management of bronchial asthma.

IP 22 Medical foods - A revolutionary approach to disease management

S.M. Meher, M. A. Nagras, N.S. Ranpise*,P.B.Miniyar & K.S.Jain

Sinhgad College of Pharmacy, Vadgaon (Bk.), Off Sinhgad road, Pune 411 041

The term "Medical Food" means a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which there are distinctive nutritional requirements based on recognized scientific principles established by medical evaluation.

An example of a medical food is a food for use by persons with phenylketonuria, i.e., foods formulated to be free of the amino acid phenylalanine.

Medical foods are not meant to be used by the general public and may not be available in stores or supermarkets. Medical foods are not those foods included within a healthy diet intended to decrease the risk of disease, such as reduced-fat foods or low-sodium foods, nor are they weight loss products.

The word Medical Food is often confused for or used interchangeably with Standardized Herbal Preparations/ Dietary Supplements/ Functional Foods/ Designer Foods/ Therapeutic Foods/ Commodity Foods/ Enriched and Fortified Foods, etc.

Until recently, medical foods received little attention. But the number and types of foods marketed as medical foods are increasing. Hence there is an increasing need for its regulation by Regulatory Bodies.

The poster will attempt to address some related aspects such as Medical Foods for Special Dietary Use, Medical Food Definition, The 'Medical Foods Paradox', Enteral Nutrition, Medical Food Indications and Claims, Specific Dietary Management, Distinctive Nutritional Requirements, Physician Supervision, Substantiation of Medical Food Efficacy Claims, Medical Food Safety and Ingredients and Future of Medical Foods.

IP 23 A Study on diabetic population in a tertiary care referral hospital in Kerala

***Nishi.G., K.G. Revikumar**

Pharmacy Practice Dept., Medical College, Trivandrum, Kerala 695 011

Various studies have shown that the diabetic population have been increasing in India in an alarming proportion during the last few decades. It is estimated that India will be one of the leading centers of the world with high diabetic population by 2010 AD. Kerala is one of the Indian states where the diabetic population is found increasing year by year irrespective of the fact that a huge majority of the people of Kerala are health conscious. Experts were trying to analyze the root cause of this 'diabetic syndrome' in the state of Kerala.

The present study was conducted from the view point of a practicing clinical pharmacist to analyze some selected aspects of the diabetic syndrome in the state of Kerala. A leading, urban centered tertiary care multi-specialty government owned teaching hospital was selected for the study which was extended for a period of six months from February 2003. About 30,000 patients came to the hospital, covering both inpatients and outpatients were randomly analyzed and studied.

Data collection was done based on a standard pre-designed questionnaire along with patient interview. Hospital wards, O.P dispensary, hospital pharmacy and community pharmacy premises were selected for the study. Interview with the treating clinicians were also conducted. The findings were compared with that of some earlier records and statistics available with the hospital authorities.

It was found during the study that 28% of all patients coming to the hospital during the period of study were with diabetics which shows an increase of nearly 4 % compared to 2000 AD statistics. About 80% of the diabetic patients were using insulin either alone or in conjunction with other oral anti-diabetic drugs. The economic aspects of the therapy or management of diabetic of various categories were analyzed. The patients were analyzed based on their age group, sex and socio-economic background. The most prevalent age group was found to be in the 50-59 years of age. The practice of drug compliance and life style adjustment among majority of the

diabetic patients covered under the study (66%) was found not satisfactory. This highlights the need and requirement of hospital oriented patient counseling centers in major hospitals in the state of Kerala.

IP 24 A Study of the drug use pattern in a tertiary care multi specialty teaching hospital

Femy George Thomas *, Manna.P.K, Mohanta.G.P, Manavalan.R

Dept. of Pharmacy, Annamalai University, Annamalai Nagar 608 002. TN

A study on the drug use pattern was carried out in the outpatient department of general medicine in Rajah Muthaiah Medical College and Hospital in a prospective randomized manner using WHO suggested Core drug use indicators. This study measured the performance of health care professionals in three general areas related to the rational use of drugs(1) the pharmaceutical prescribing practices,(2) key elements of patient care including both clinical consultation and pharmaceutical dispensing (3) availability of facility specific factors such as the access to key essential drugs and minimum pharmaceutical information. A total of 720 outpatient prescriptions containing 2,592 items from March 2003 to August 2003 were analyzed with the core drug use indicators during the study. Among the prescribing indicators, the average number of drugs per prescription was found to be 3.6, percentage of drugs prescribed in generic name 48.8 %, percentage of encounters with an antibiotic prescribed 86.6 %, percentage of encounters with an injection prescribed 18 %,and percentage of drugs prescribed from essential drugs list or formulary 78 %.In the patient care indicators average consultation time was found to be 2.6 mins per patient, average dispensing time 85 secs per patient, percentage of drugs actually dispensed 89 %,percentage of drugs adequately labelled 45 %,and the patients knowledge of correct dosage 44 % .Among the facility indicators namely the availability of key drugs and availability of copy of essential drug list or formulary, it was found that though an essential drug list or formulary was not available all the key drugs were available. The prescribing practices and the patient care factors studied here measure the performance of health care providers in key dimensions related to the rational use of drugs. From the results of the present study it is observed that drugs prescribed from essential drug list or formulary (78%) in the absence of both in the facility is quite satisfactory; while generic prescribing (48.8 %),antibiotic prescribing (86.6 %),consultation time (2.6 mins per patient),average dispensing time (85 secs per patient)adequate labelling (45 %), patients' knowledge of correct dosage (44 %) are quite unsatisfactory. Performance in these areas can be significantly improved by the intervention of clinical pharmacists. The authors plan an intervention study for better drug utilization at the facility, for which results of the present investigation will serve as baseline data.

IP 25 Epidemiological study of Epilepsy in selected communities residing in Madurai

Abraham Kuruvilla, Narmada Sambasivam*, Sundaramoorthy, M.Murugesh.**

K.M.College of Pharmacy, Madurai Medical College**, Madurai.

As we find an increase in the prevalence rate of epilepsy and there are many causative factors for epilepsy, studies have to be carried out to find out major predisposing factors causing epilepsy. Among the various causative factors, consanguineous marriages is one of the main factor. Here a survey on two major communities living in clusters in Madurai city was carried out to study the incidence of epilepsy and etiology of the disease.

Sourashtrians living in Thavittu Santhai, Villapuram and Muslims in Mappalayam area in Madurai were surveyed using two validated questionnaires, one to find out incidence and another to assess pattern of epileptic seizure and etiology of the disease.

Study showed that prevalence was very high in both Sourashtra and Muslim population 1.006% & 1.91% as against standard reference value 0.5%. Primary epilepsy was more common (87.09%) than secondary epilepsy (12.90%) in Sourashtra population whereas it was 55.1% & 44.89% in Muslim population. Consanguineous marriage (30.61%) was a major etiological factor with other factors contributing comparatively to a lesser extent - Granuloma (14.28%), Mental retardation (12.24%) & Head trauma (10.20%) in Muslims, with mental retardation 6.5% and cerebral atropy 3.25% in Sourashtra community. Female patients were found to be more than males in Muslim community.

The study indicates the need for community education about the factors influencing epilepsy and to avoid the same.

IP 26 Study of the usage of antibiotics in acute suppurative otitis media at Victoria HospitaL, Bangalore

Shaji Mathai*, Shobha Rani.R.H, Satish H.S, Nagraj E.R

Al-Ameen College of Pharmacy, Bangalore

Suppurative otitis media refers to a clinically identifiable infection of the middle ear. It may be acute or chronic. Otitis media has been identified as the

most frequent reason for outpatient antibiotic therapy and the widespread use of oral antibiotics to treat otitis media has resulted in an alarming increase in antibiotic-resistance. The present study was taken up with the objectives of the type of antibiotic used and the extent of antibiotic usage in Acute Suppurative Otitis Media at Victoria Hospital and evaluate the anti bacterial sensitivity pattern to the antibiotic used in Acute Suppurative otitis media at Victoria Hospital .Consecutive 100 outpatients to the ENT Dept with a diagnosis of Acute Suppurative otitis media formed the study sample. A detailed history of each patient was taken. Pus specimens were taken with the help of sterile cotton wool ear swabs from the infected ear of the patients and processed in the Department of Microbiology. Based on the results, the right choice of Antibiotic was selected. The most commonly prescribed antibiotic was found to be Amoxicillin followed by Roxithromycin

Amoxicillin remains the drug of choice, as it is the most commonly prescribed drug. However, culture sensitivity test found in the middle ear specimen are resistant to Amoxicillin, which may lead to treatment failures. The rationale of using Clotrimoxazole and Cephalexin is doubtful as most of the organisms are found to be resistant to both. A Meta analysis of literature also reveals that Azithromycin is a reasonable choice of antibiotic acute otitis media.

IP$_{27}$ The prospective study on the extent of compliance among elderly patients

S.Annadurai*, Prasad Mathews and M.Thangadurai

*Dept. of Pharmacy Services, Christian Medical College, Ida Scudder Road, Vellore 632 004, Tamilnadu.

Medications are probably the single most important health care fruitful system outcome in preventing illness, disability and death in the geriatric population. New pharmaceutical products provides hospital pharmacists with valuable tools for upgrading quality of life but also confer upon them the more difficult task as well as the greater responsibility of balancing clinical effects to contribute the highest possible quality of life for the elderly patients. With the steady increase of advanced medical disorders along with the drastic surge in the number of marketed prescribed drugs, patient compliance to medication regimens has become increasingly complicated and problematic. The main objective of the study is to find out the extent of compliance among geriatric patients and to determine whether there is any significant association between demographic, socio-economic status, awareness about the disease and other variables with non-compliance. The outcomes of the methods which could improve the compliance are also suggested. Elderly patients above the age of sixty years who had attended Medicine Unit of Christian Medical College and Hospital for the treatment/review and Out-patient pharmacy dispensing counter were included in the study. An interview was conducted with each patient based on a semi-structured questionnaire which consists of questions about demographic, socio-economic, cognitive skills, treatment schedule, awareness about the disease/disorders and so on. The data collected were statistically analyzed and determined whether there is any significant association of the variables with regard to the non-compliance. The data collected through the quantitative questionnaire was analyzed on the basis of their extent of non-compliance. The compliance score was calculated using two aspects, one on the number of days on medication and the other on the total days prescribed with medicines. Accordingly, the elderly patients were categorized as excellent compliant patients [100%], good compliant patients [90-99%] and non-compliant patients [< 90%]. The several risk factors associated with the patients' attitude contributed to the percentage of compliance are also identified with regard to therapy, patient-physician relationship and primarily the patient related factors [understanding of the prescribed medications, the magnitude of low compliance, etc]. The results showed that out of 100 patients, 27 were found to be excellent in compliance, 39 as good in compliance and 37 were non-compliant. Age and other related risk factors found have significant influences on their extent of compliance.

IP$_{28}$ Study of prescribing trend in respiratory tract and urinary tract infections in the district of Cuttack, Orissa

D.M. Kar, D. Sahoo*, J.Malick and G.R. Dash

Department of Pharmacy, Utkal University, BBSR.

There is no fixed guidelines for antibiotic usage in our country. WHO gives guidelines for use of antimicrobial agents may not be exactly implemented in current therapeutics practice. So, this study focused on the usage of antibiotic regimens in the treatment of RTI and UTI in adult in context to WHO guidelines.

This study consists of three parts: Survey of antibiotic usage (Data was collected from 50 drug stores out of 1000 prescriptions in Cuttack district), Opinion of 100 prescribers (about their choice of antibiotics to treat commonly occurring infections), Development of cross resistance and patient non-compliance. Analysis of prescriptions reveal that RTI is most common comprising half of the total prescription, out of which about 80% are from urban areas. The prescribers prefer Cephalosporin, Fluoroquinolones and Azithromycin followed by Roxithromycin, Erythomycin and Ampicillin +Cloxacillin for URTI. In case of LRTI Cephalosporin is more prescribed drug among them. Fluroquinolons is frequently used drug, followed by Cephalosporin, Gentamicin and other antibiotic in case of UTI.

Antibiotics used for above diseases are different from WHO recommendations. It may be due to the lack of knowledge of prescribers or to promote the sale of new drugs or to satisfy patient in quick relief from disease.

IP29 Pattern of tobacco use and nicotine dependence in rural India

Chikku. A. Joseph*, Rendeep Rajendran, S.Ponnusankar, S.D. Rajendran, B. Suresh

Dept. of Pharmacy Practice, JSS College of Pharmacy, Ootacamund 643 001

Nicotine is an addictive substance. It is the only drug which has both stimulative and depressive property. It is estimated that the number of addictives will be 51.073 millions in 2025 from 48.534 million in 2000 as per WHO. The incidence of lung cancer is 8 / lakh and 1.7/ lakh in males and female in 1990.A death due to tobacco use in developing countries is 129/1000. Percentage of total deaths 1.4% and percentage of total years of life lost is 0.6 years estimated by WHO. As per recent published WHO survey, in 2020 death due to tobacco use alone is 1523/1000 and percentage total years of life lost will be 12 years. The potential health benefits of smoking cessation are substantial since it is studied that half of regular smokers die prematurely of tobacco related diseases. Hence the study was conducted to assess the magnitude of prevalence of tobacco use and nicotine dependence and related health consequence in and around Ooty Coordinator assisted standard pre-evaluated questionnaire was subjected to the randomly selected male population (prospective)

The data were analysed as per laws, total estimated cigarette consumption, annual per capita cigarette consumption and consumption based estimate of the average number of cigarette smoked per smoker per day were calculated The following prominent true facts were revealed 9.32% smokers were below the age of 20, 52.78% smokers were govt/ private employers.73 % were educated 75.3%were cigarette smokers, 82% suffered from asthma and dependence,80% with bronchitis,67%with severe cough and 66% with peptic ulcer.

IP30 Evaluation of the quality of services provided by the drug information center of Kasturba Hospital, Manipal

Padma GM Rao, Sapna Gore,* Deepa V

Department of Pharmacy Practice, College of Pharmaceutical Sciences, Manipal-576104

A total of 395 queries were received during the study period. Out of 50 randomly selected queries 25 each of judgmental and non-judgmental type were evaluated. The queries were rated from 1 to 5, 5 indicating that the information given was excellent and 1 indicating that significant deficiencies made the consultation unacceptable for use. In the judgmental type maximum number of queries 13 (52%) received the rating of 4 which means the consultation was very good and minor problems with documentation, comprehensiveness, timeliness, writing or other important aspect existed. In non-judgmental type maximum number of queries 11(44%) received the rating of 4 which means that other than a minor problem with documentation, comprehensiveness, timeliness, or other important aspect, the response was very good. Results from the feedback questionnaire showed that almost all of the enquirers were satisfied with the quality of drug information provided to them. Most of the queries answered by the center were within the acceptable quality. However improvement in answering the judgmental queries is required. The drug information feedback questionnaires from the various enquirers revealed that 90% of the responders utilized the services effectively which was up to the expectations of the enquirer with respect to time, appropriateness and quality of the services.

Improper functioning of the drug information center can result in inappropriate information, which can contribute to poor patient outcome in terms of health and economics. Periodic evaluation of such services to assess the mode of functioning and quality of service is important.

Quality of the drug information provided by the drug information center of Kasturba Hospital, Manipal was evaluated for duration of 6 months from September 15th 2002 to March 15th 2003. To evaluate the center on the basis of provision of drug information, guidelines from DSE/WHO seminar was adopted. To evaluate the center on the basis of outcome a feedback questionnaire was prepared and distributed among the clinicians of the hospital, and the filled questionnaire was collected.

IP31 Study and evaluation of the adverse drug reactions in dermatology department of Kasturba Hospital, Manipal

Siddhartha Ghosh, Leelavathi D Acharya*, Padma G. M.Rao

Department of Pharmacy Practice, COPS, Manipal - 576 104

Drugs no matter how safe and efficacious are always coupled with inescapable risk of adverse reactions. Adverse drug reactions(ADRs) are a cause of significant morbidity and mortality in patients of all areas of healthcare today. It has been estimated that from one third to as high as one half of ADRs are believed to be preventable. Cost of morbidity due to drug related event was recently estimated to be $76.6

million, annually. However the suffering that the patient experiences because of drug related events cannot be quantified.

Cutaneous ADRs are the most common among the various adverse reactions attributed to drugs. Any skin disorder can be imitated, induced or aggravated by drugs. The incidence of cutaneous drug reaction varies from 15 to 30%.

The objective of this study was to implement an ADR reporting and monitoring system in the department of dermatology, to categorize and analyse the most common drugs and various predisposing factors attributed to the occurrence of ADRs, and to assess the causality of the same. During the study period(Nov 2002 to April 2003), a clinical pharmacist was posted in the different units of dermatology. Different promotional activities were carried out to implement ADR reporting and monitoring system in the department of dermatology. All the ADRs were reported and documented with the help of clinicians in recognizing them. Documented ADRs were assessed and analysed. Main outcome measures were incidence, age - related variation, attributed drug class and type of reaction, probability, severity and outcome.

The frequency of ADRs in these patients were 2.85%. Most of the ADRs were of type H category. Amoxicillin(6), acetaminophen(6) and phenytoin were the most commonly associated drugs and antibiotics were the most common drug class associated with ADRs. The most common type of reaction was maculopapular rash(67%). According to causality, 10% of the ADRs were regarded as definite, 47% as probable, and 41% as possible. The majority of ADRs were moderate(52%) and 27% were severe. The main treatment of the ADRs was the withdrawal of the suspected drugs. Among 53 ADRs, 41 patients who visited hospital because of ADRs. Study concludes that ADR attributes to a significant percentage of hospital visits in dermatological population. Antibiotics, analgesics and antiepileptics were most commonly associated with cutaneous ADRs. Most of the reactions were of moderate severity and could be managed by the withdrawal of the drugs.

IP 32 Pattern of use of oral rehydration therapy among mothers in tribal area of Dhule district

Chauk D.S., Patil P.N.*, Patil S.B., Mahajan H.S.,Wagh R.D

A.R.A.College Of Pharmacy, Nagaon. Dist. Dhule.

To assess the knowledge of preparing oral rehydration salt solution [ORS] and salt sugar solution among mothers of Dhule district.

A community based cluster study was conducted. A total of 250 mothers were interviewed using a questionnairres [prepared in regional language]. Mothers were educated to correctly prepare and administer Oral Rehydration Salt solution and salt sugar solution.

Mean age of mothers was 32.98yrs [SD+6.5]. About 35% mothers were uneducated. Only a small proportion of mothers recognized ORS packets 8.90% and 7.56% mentioned the correct method of preparing a solution. Salt sugar solution preparation was adequately described by 7.8% of mothers.

This study clearly indicates that oral rehydration therapy is not effectively known in this region and the reason for this was lack of education. Therefore, it is strongly recommended that well designed educational programme should be carried out to improve the knowledge of mother in using oral rehydration solution in treatment of diarrhoea.

IP 33 Medicine usage patterns in public primary health care clinics

George K John*, Martie S Lubbe* and Jan HP Serfontein*

* Pharmacy Practice, School of Pharmacy, Faculty of Health Sciences, Potchefstroom University, Potchefstroom, South Africa.

The objective of this study was to present the usage patterns of medicines at a primary health care level in the public sector. The results were then used as a planning and control instrument for the usage of medicines in regards to demand-procurement and inventory controls strategies.

The WHO model for investigating medicine use in health facilities was adopted as the model for this study. A retrospective sample of 1313 patients visiting six local authority primary health care clinics in Potchefstroom was selected. The medicines used by these patients were coded using the proposed medicine budget group, pharmacological groups, individual item descriptions and the ATC classification system.

The interpretation of the results showed that the overall gender frequency was 26.47% males and 73.53% females, the five most prevalent diagnosis/ conditions excluding tuberculosis were family planning (15.72%), hypertension (11.94%), vitamin deficiency (9.77%). Pain control (9.62%) and malnutrition/lactation regulation (8.32%) and the five most prevalent medicine items used for all consultations excluding anti-mycobacterials were Pyridoxine [Vit.B_6] 5 mg tablet (7.02%), Vitamin B complex tablet (6.25%), Hydrochlorthiazide 25 mg tablet (5.95%), Paracetamol 500 mg tablet (5.44%) and PVM Maize meal mix [1kg] (5.11%).

It was concluded there could be an overuse and tendency to prescribe vitamins and feeding supplements to the patients regardless of the clinical merit, the prevalence and use of anti-hypertensives in

the clinics where high and that the possibility of over prescribing of non-opoid analgesics in the clinics cannot be ruled out.

The implementation of similar studies is encouraged for better report and data management, improved procurement-demand-inventory control strategies and ways to evaluate clinical and operational policies in the public primary health care sector.

IP 34 A study on self-medication practices in the State of Sikkim

*** Suvakanta Dash, D. Dhachinamoorthi, Ajeya Jha**

Himalayan Pharmacy Institute, Majhitar Rangpo, Sikkin 737 132

Sikkim, the second smallest State of India and a part of north eastern Council is located in the north of West Bengal. It became a part of India as recently as 1975. Though about 28 years have passed, yet Pharmacy act has not been implemented in the State. The main objective of the study has been (a) To overview the medication patterns and practices in Sikkim (b) To identify the factors affecting it. The study was randomized by adopting the probability proportion to size technique. Those surveyed included (i) 300 patients (ii) 50 physicians (c) 75 retail drug distributors (d) 80 other health professionals. The study was conducted in both urban as well as rural areas using planned questionnaire.

The Study reveals many interesting and yet critical aspects of self-medication. It was found that 85% of the Population under survey use herbal treatment. 8% of the surveyed people consult physicians only once. A large number of patients depend upon either the retailer of medicine shop or on literate/educated people.

Present study indicates that the self-medication rate was much lower in rural population than in urban population. Among the categories of drugs that are used often for self-medication include Antibiotics 12% in rural areas and 15% in urban areas, Gastrointestinal drugs 38% in rural areas and 42% in urban areas, Analgesics and antipyretics 36% in rural areas and 75% in urban areas. During the study it was found that as many as 95% of the shop owners selling medicines have inadequate knowledge of medication. Yet the customers (patients) have substantial faith on medical shop owners and they continue to take medicine according to their advice.

At last, data was collected from different physicians and other health professionals for their opinions regarding requirements of qualified pharmacy professionals in the state, for pharmacy practice as well as requirement to implement pharmacy act. It was found that about 94% of the physicians agreed that qualified pharmacy professionals should practice pharmacy in the State, similarly 65% of other health professionals felt duly qualified persons are vital for dispensing of drugs in the State.

Based on these findings, it is proposed

(a) Extensive awareness programmes need to be launched to achieve better health care to the patients of the State.

(b) Pharmacy act must be implemented in the State immediately.

(c) Encourage substantial students in the State to qualify as pharmacist and serve their State.

Resources persons in the State should be identified and motivated to ensure good pharmacy practices.

IP 35 Impacts of myths on diabetes management

D.M. Kar, N.R. Pani, S.S. Rout*, B.K. Behera, P.K. Biswal

Univ. Dept. of Pharm. Sciences, Utkal University, Orissa.

Diabetes is now seen as a heterogeneous group of disease characterized by a state of chronic hyperglycemia resulting from a diversity of aetiologies, environmental and genetics or acting jointly. Now a days various myths on diabetes disease and treatment become has hurdle in diabetes management, which need to be clarified by the health concerning persons including pharmacists.

The present study aims at accessing the prevalence of diabetes on various age groups, sex and economic status of the patients. However it also estimates the different myths of the patients regarding disease and treatments in the recent clinical practice. The work may provide feedback to pharmacists and other health concerning persons for better management of diabetes.

Data was collected through direct interview and prescription study of 156-diabetes patient visited to OPD, DHC (Anugul, Orissa) for period of 15 days (from July 31 to august 14) to know the prevalence of types of disease on the socioeconomic status, age and sex. It however results the awareness among the people, & role of pharmacists on the management of disease and compliance to prescription.

Current survey shows that the disease mostly occurs in middle class family that of age group above 60 years with nearly equal important of both sexes. In current trend of diabetes therapy, not a single drug has claimed to cure the disease. In addition with this, development of myths on the disease & its treatment make the therapy more complicated and increase the noncompliance to the prescriptions. In this regard not only pharmacists, every health personnel need to motivate the patients on the facts of the myths and to improve the patient compliance to prescription.

IP 36 Retrospective studies on type-II Diabetes mellitus

Nagpal Ankita, Kumar Sanjeev, Singh Shashank, Garg Arun, Agarwal S.S.

College of Pharmacy, Pushp Vihar, Sector 3, New Delhi 17.

The world is experiencing a rapid increase in the prevalence of Diabetes mellitus, a common chronic disease, if not properly manage diabetes can lead to wide range of complications that have clinical social and economic implications so there is great need manage this disease by proper diagnosis medication, proper diet and exercise rationale of drug prescription, retrospective analysis of prescriptions. The Retrospective studies includes, Survey of prescriptions comprising patients complete medication records. On the basis of prescriptions data were generated and statistically evaluated. The trend analysis suggests the optimum drugs available for disease specific. Our study includes Retrospective studies on the prescription pattern of Diabetes mellitus which was conducted at All India Institute of Medical Sciences, New Delhi. The aim of the study was to review the Drug utilization for enhancing the quality of Drug Therapy in type II diabetes mellitus. We have collected the prescription files at random from the hospital records. 122 Prescription files containing patient profile including serum, sugar and lipid profile, diet chart, Drug therapy and risk factor were examined. All the data were generated on the basis of questionnairres developed. The retrospective study on patient of NIDDM suggest: The criteria for obesity is a BMI more than 25Kg/m. accordingly 51.11% of diabetic population is obese. 13.59% of diabetic populations have been affected by type-2 diabetes at a lower age group of 40-45 yrs. Most of the cases are of complicated diabetes requiring oral anti-diabetic drug for control of diabetes with dietary modification alone. 39.34 of the patient are being treated with combination therapy like sulphonyl urea and metformin, 35.245% of the patient are being treated with monotherapy. Among the sulphonyl ureas, Glibenclamide (61.33%) and Gliclazide (28%) are most prescribed drugs. Hypertension and CAD are common concomitant disease with Type-2 diabetes (32.03% of type-2 diabetes patient have associated hypertension). The study reveals that the most common disorder with type-2 diabetes are HT, CAD, and Obesity. The most popularly prescribed drug in the treatment of type-2 diabetes are sulphonyl ureas. In many cases the alternative approach is life style and dietary modifications to improve the Quality of Life in Diabetic patients.

IP 37 Nutraceuticals : Are they true calorie substitutes

Manmeet Kaur*, Manas Jyoti Bharadwaj, Raman Dang

Al-ameen College of Pharmacy, Hosur Road, Near Lalbagh Main gate, Bangalore 560 027

A nutraceutical is a food / part of a food that offers medical and / or health benefits including prevention or treatment of diseases. Nutraceuticals range from isolated nutrients, dietary supplements and diets to genetically engineered designer foods, functional foods herbal products and processed foods such as cereals and soups including certain beverages.

Survey was conducted at the pharmacy shops, health clinics and various doctors and consultants were interviewed. Most of the results showed an upward movement of these products. The sale and consumption of these products was seen to be higher. Patient awareness was observed due to the promotion of nutraceuticals through various advertisements and media. Various techniques to promote nutraceuticals in Indian Market were developed through expert assistance. Its export potential was studied and analysed. .

IP 38 Rational use of antibiotics during pregnancy and lactation

Ghulam Moinuddin*, S. Gayathri Devi£, Devesh Mishra, Sameera Mohammed Sadiq, Roy Rajan Abraham£.

* Department of Pharmacology & £Department of Pharmaceutical Marketing and Management, Al-Ameen College Of Pharmacy, Near Lalbagh Main Gate, Hosur Road, Bangalore - 560027.

The awareness of the inherent risks related to antibiotic usage during pregnancy and lactation is increasing. The main objective of the study was to assess the rationality of frequently prescribed antibiotics in pregnancy and lactation, and the degree of patient compliance.

A prospective analysis was conducted on 168 pregnant women (PW) and lactating mothers (LM), interviewing 100 OB/GYN doctors in government and private hospitals in Bangalore. One part of the study included interviewing the OB/GYN doctors. The second part of our study included brief interaction with 80 pregnant women and 88 lactating mothers and getting the questionnaire answered separately.

All the PW and LM were prescribed a combination of folic acid/multivitamins, iron, and calcium supplements. The next most commonly

prescribed drug category was antibiotics (92%). 43% of all the lactating mothers received sedatives. 97.23 percentage of OB/GYN doctors recommended pregnancy tests. 82.5% recommended tests for infections prior to prescribing antibiotics.

The most common medications prescribed during first trimester were amoxycillin and ampicillin, a combination of amoxycillin plus cloxacillin during second trimester and erythromycin during third trimester. Over 92% of women were multigravidas in the entire sample size.

Most patients who underwent cesarean section (CS) received antibiotics and NSAIDs (44%). Among the women receiving antibiotics, 55.4% received it for prophylactic use and 45.6% for therapeutic use. 70% of women who had a normal delivery received antibiotics. 3-4% of the lactating mothers received metronidazole, which is contraindicated during breast-feeding.

Neither pregnant women nor lactating mothers were aware of the probable adverse drug reactions, drug-drug interaction, teratogenicity, drug resistance, which are the results of irrational drug therapy.

IP 39 A study on adverse drug reactions (ADRs) related hospital admission and their management

R. Rajesh, M. Ramesh and G. Parthasarathi

Department of Pharmacy, JSS College of Pharmacy, Mysore -15.

Adverse drug reactions (ADRs) related hospital admission is a major health concern, ADRs make a significant but potentially avoidable contribution to inpatient morbidity and mortality. This study aimed to assess the nature, causality, severity and management of adverse drug reactions related hospital admissions.

This was a prospective, spontaneous reporting a study conducted over a period of seven months. The World Health Organisation (WHO) definition of an ADR was adopted. Each ADR was assessed for its causality and severity by using WHO probability scale and Hartwig scale respectively.

A total of 316 suspected ADRs were reported and evaluated from 126 patients. The incidence of ADRs related hospital admission was found to be 0.56% and 1.89% of adverse reactions were fatal in nature. The drug class most commonly implicated with ADRs was antibiotics (24%) whilst rifampicin was the most (7%) implicated drug in causing ADRs. The system most commonly involved with an ADR was the dermatologic system (62%). Most commonly reported reaction was rash (32%). Most (69%) of the reported ADRs belonged to the category of `Probable'. Majority (97.75%) of reported reaction were moderate in their severity. Majority (56%) of reactions were predictable and 33% of reactions were preventable. Withdrawal of the suspected drugs was the main line of management in 90.18% of cases.

As majority of these adverse reactions are predictable & often preventable, there is a need for a greater awareness among the healthcare professionals regarding prevention (or) minimization of occurrence of ADRs related hospital admission.

IP 40 Medicine management & medicine education by pharmacist through value foundation

Ravindra D. Waykar*, Sachin C. Itkar, Madhav P.Patil, Amoldeep G.Shinde

Pradhikaran, Nigdi, Pune 411 044, Maharashtra

Pharmacy is a profession to which the control of medicine is attributed; it should be involved intimately with those activities that aim at preventing or reducing medicinal use & its related problems.

It is unfortunate that, on the whole, pharmacy has been lacking in its social responsibility for the medicinal substances.

Medicine management / education need of the hour: In today's highly complex, technological world, the availability of appropriate & precise information allows one to understand, to make better choices & to prevent or solve problems.

Medicine management & Medicine Education is one of the objective to serve community can create awareness in community. Profession gets status only when it serves community.

So pharmacists should identify the objective for securing community& medicine management by pharmacist through value foundation

When medicine is prescribed for a patient, health professionals expect that the drug will be taken precisely as directed.

But goals of therapy will not be reached if there is non-compliance by the patient.

The pharmacist is the last health professional to see the patient prior to the time the medication is to be administered.

Hence the Pharmacist is in an excellent position to assume a major responsibility in medicinal education & medicine management.

Experimental Work Done;

A drug education program held in a hospital co - ordination with hospital staff & Students Pharmacists through the value based counselling following results are obtained.

IP 41 Effectiveness of clinical pharmacist counselling on knowledge, attitude and practice of COPD patients - A multicenter study

Sathvik B.S*, Manohar Steven Pinto, Shilpa Palaksha Sabin Thomas, Parthasarathi G

Dept of Pharmacy Practice, JSS College of Pharmacy, SS Nagar, Mysore-15

COPD is an irreversible chronic airway disease demanding a high level of patient care. Studies have shown that patients who perceive themselves as being well educated about the disease are more likely to be satisfied with their health care experience.

To assess knowledge, attitude and practice of COPD patients regarding their disease, drugs and inhaler techniques; to provide counselling and training to COPD patients about their disease and medication use; and also to prepare and provide patient education leaflets on disease and benefits of quitting smoking.

Knowledge, attitude and practice (KAP) Questionnaire was administered before and three months after the patient education.

Three tertiary care hospitals of Mysore city

Patient education improved the KAP of the patients and they were able to answer satisfactorily the same questions when compared to the baseline. About 92% patients answered that smoking is a risk factor for COPD and 92.45% answered that COPD patients should stop smoking. About 92% believed that smoking is a cause of COPD and 100% of patients knew that COPD is non-contagious. Their medication practice improved and 98.11% answered that COPD patients should take medicine regularly; 100% practiced regular medicine use. By the end of the study, all patients on inhalers found them easy to use and were performing the first step in using an inhaler properly.

Our study findings suggest that patient counselling improves knowledge, attitude and more importantly practice of patients with COPD.

IP 42 ABC analysis of drug utilizations in a secondary Care Hospital in Tamil Nadu, Ootacamund, The Nilgiris.

Juno J.Joel*; Senthil R; Maneesh S. Sarvi; Rajendran S. D; and Suresh. B

JSS College of Pharmacy, Ootacamund

ABC analysis is a technique in which the principle is to concentrate on few vital items and ignoring many trivial items, which will help to avoid absolute carelessness in inventory situation and determines the importance of items and the level of controls placed on the items.

This technique was used to analyze the drug utilization in Government Head Quarters Hospital, Ooty, The Nilgiris. The data were collected for four consecutive years from 1999-2000 to 2002-2003. These were divided in to three categories, viz., Category A which constitutes 80% of budget, category B that constitutes 15% of budget and category C which constitutes 5% of budget.

Amoxycillin consumed 19.8% of hospital budget in 1999-2000 and 17% in 2000-01. Insulin consumed 12.5% of budget in 2001-02 and 10.48% in 2002-3. The toppers in consumption at the hospital were Amoxycillin, ascorbic acid and Cefotaxime in 1999-2000, Amoxycillin, insulin and Ciprofloxacin in 2000-01, insulin, Cefotaxime and Cephalexin in 2001-02 and insulin, Amoxycillin and intravenous fluids in 2002-03. A trend towards increased consumption of insulin has been observed. Further investigations are being carried out to identify the reasons for increasing consumption of insulin.

IP 43 Evaluation on the relative efficacy and safety of once daily dosing Vs. Multiple daily dosing of aminoglycosides

Shaji George*, S.S. Shriram, A.S. Manjula Devi, Jeobu Peter & T.K. Ravi

Dept. of Pharmacy Practice, College of Pharmacy, CRIMP, 395, Sarojini Naidu Road, Coimbatore 641 004, TN

In recent years, once daily administration (ODA) has been used increasingly, in hope of both improving efficacy and reducing toxicity. A randomized trial was carried out in a 400 bedded Multi-specialty Hospital in three phases viz.: 1) Inventorial phase in which a comparison was done between ODA and MDA (multiple daily administration of aminoglycosides) for its safety and efficacy. 2) Implementation phase in which the implementation of ODA dosing program was done in the hospital by educating the medical and para-medical professionals, through clinical meetings, circulation of Aminoglycoside dosing guidelines etc 3) Post Implementation phase in which effectiveness and acceptance of the implementation programme was assessed. The patients were randomized to receive aminoglycosides once daily or twice daily with similar total daily dose. During the study period 172 patients received aminoglycoside therapy, out of which 49 evaluable patients were considered for renal assessment. The incidence of nephrotoxicity was 1(4%) with ODA program and 5(23%) with MDA program. The p-test value was 2.021 ($p<0.05$) which is significant at 5% probability level. 20(74%) patients showed improved or stable renal function in ODA

programme compared to only 8(36%) with MDA program. Decreased renal function was seen in 7(26%) with ODA and 14(64%) with MDA. On the basis of prospective evaluation and follow-up via Clinician's report, it was noted that no apparent alterations in clinical response was seen with the ODA program. Thus once daily administration of aminoglycosides is as effective as multiple daily dosing, has a lower risk of nephrotoxicity and no greater risk of ototoxicity.

IP 44 A study on the importance of patient counselling in asthma and inhalation therapy

Shijin P. R, Simi. T*, Uma Maheswari. M ,T.K.Ravi

Dept. of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore

Patient education has an inevitable role in the succesful management of asthma. Clinical pharmacists are in a pivotal position to contribute to the overall management of asthma. Pharmacist can educate patients about asthma medication, instruct patients about proper technique for inhaling medication and to help patients discharged from the hospital understand their asthma management. The study was conducted at a private corporate hospital, Coimbatore for a period of six months during this period the patients admitted to the department of pulmonology and critical care and diagnosed of bronchail asthma were studied in two phases- implementation phase and post implementation phase. Data entry forms were designed on the basis of collecting information about patient details, lab investigations and drugs prescribed. A questionnaire for the assessment of patients perception and an inhaler assessment check list were prepared. As the demonstration of correct inhaler technique is essential placebo inhalers were used in the study. The implementation phase was carried out using the questionnaire which had two parts (a) assessment of patients perceptions and (b) assessment of patients inhaler technique. A written individualized asthma action plan was prepared and distributed to the patients. The impact of the instructions and demonstration using placebo inhaler by the clinical pharmacist on the inhaler technique of the patients were assessed in the post implementation phase.The results of the two phases were analysed and informed to the chief pulmonologist and it revealed the importance of pharmacist role in patient counselling.

IP 45 Provision and evaluation of drug information services at a Tertiary Care Hospital in Bangalore

***Kavita K. Gopal & Shobha Rani R.H.**

Department of Pharmacy Practice, Al-Ameen College of Pharmacy, Bangalore

Developing countries suffer from lack of adequate drug information. A teaching hospital-based DIC can be of assistance in patient care/educational activities by providing unbiased DI.

Drug information is provision of written and/or verbal information or advice about drugs and drug therapy in response to a request from other healthcare providers, organizations, committees, patients or members of the public.

DI Request and Documentation Forms were prepared. Awareness activities were conducted in Departments of the hospital. DI queries of Allopathic System were received via any of the modes of request. Answers for queries were formulated and reply was communicated to enquiriers. Reports sent were documented. Quality of reply was assessed using feedback forms and audits.

DI Services were utilized by various specialities. Majority of queries out of 200 in 10 months, were received by direct access/during ward rounds. Purpose of queries was updating knowledge/better patient care and research. The query category was drug therapy, disease management and recent advances. Resources consulted included Tertiary/Secondary/Primary. Mode of information provided was frequently verbal and printed material. On follow-up most enquirers found the information to be informative and adequate.

Maximum number of queries was received in initial six months. Clinicians felt the need of a clinical pharmacist in their health care team to solve clinical problems in daily practice especially in adverse drug reactions, interactions and dosages of uncommon drugs. Provision of Drug Information Services can play an important role in providing necessary and vital information to the Clinicians in helping them make sound judgement.

IP 46 Biochemical and hematological assessment of ethanol toxicity in humans

K.Senthilkumar, S.Palani, S.Raja, S.Baranidaran*, M.Bakkiyaraj, R.Varadarajan, R.Gandhimathi, N.Gnanasekar

Kamalakshi Pandurangan College of Pharmacy, Ayyampalayam, Tiruvannamalai-606 603 T.N.

To assess the metabolic alterations caused by ingestion of alcohol, estimation of cellular constituents and blood parameters followed by estimation of various enzymes.

Marked elevation of serum in alcoholic patient usually denoted the presence of biliary tract obstruction or space occupying lesions with in the liver. However, in few patients, alcoholic hepatitis and cirrhosis present with a marked hyper phosphatesemia due to intrahepatic cholestatis.

The alterations of serum markers, lipid profiles and haematopoietic systems as target of ethanol toxicity. Further studies are needed to delineate the advantage of modulators supplementation in overcoming the problem of ethanol administration to humans.

IP 47 Antimicrobial sensitivity studies of urine sample of urinary tract infected patients of Ahmedabad

S. I. Patel*, N. J. Patel, M. M. Patel, J. L. Patel

Shree S. K. Patel College of Pharm. Edu. and Research, Ganpat Vidyanagar, Kherva-382711, Mehsana.

Urinary tract infection (UTI) is one of the commonest problems in all age groups although the prevalence varies markedly. It is most prevalent amongst young and middle aged women, when women reach adulthood. The prevalence of bacteriuria rises to 3 to 5 %. Each year about a quarter of the bacteriuric women clears their bacteriuria spontaneously and it is replaced by an equal number of newly infected women also. Atleast 10 to 20 % of all women will have a symptomatic UTI during their lifetime. In the elderly the prevalence of bacteriuria rises dramatically to 20% for woman and 10 % for men.

In acute uncomplicated UTI, the community Escherichia coli is the commonest causative bacterium. Other gram negative enteric bacteria such as Klebsiella and Proteus and Gram positive cocci particularly *Streptococcus faecalis* and *Staphylococcus saprophyticus, Pseudomonas aeruginosa,* Enterobacter and Serratia are more commonly isolated in hospital acquired UTIs including those in patients with urinary catheters.

Antimicrobials are commonly prescribed in UTI. development of resistance occurs with many microorganisms in overdose and repeated use in relapse cases of antimicrobials. In the light of these, we analysed 66 samples of urine for culture sensitivity study from patients with UTI at Ahmedabad. Covering all populations, various bacteria detected in samples were *E. coli, Proteus vulgaris, Klebsiella, Staphylococcus aureus,* Enterococci and Pseudomonas aeruginosa. Infection with *E. coli* was found more in comparison with other organisms.

IP 48 Assessment of prevalence of risk factor in counselling and evaluation of the significant role of cardiac markers in myocardial infarction

Kumar. E. P, Maneesh S. Sarvi*, Senthil. R, Sugin Lal Jabaris, Rajendran. S. D, Suresh. B

Department of Pharmacy Practice, JSS College of Pharmacy, Ootacamund

Myocardial infarction (MI) is a leading cause of death in men than in women. Approximately 50 million deaths occur through out the world each year. WHO indicating, higher prevalence in India than in many other developing countries. The prevalence of CAD in India varies between 7-14%in Urban, 3-5% in rural population. As per the WHO recommendation, the diagnosis of MI is based on ECG and Cardiac Markers like Creatinine Kinase (CK) Creatinine Kinase-MB (CK-MB), Lactate Dehydrogenase (LDH) and Troponin 1 and II.

The present study was carried out in Government Head Quarters Hospital, Ooty, the Nilgiris, and Tamilnadu, India. The patients blood samples (1, 6, 12, 24,36,48,72 hrs and from 4th day onwards, one sample per day till the patient discharged) were analysed for the cardiac markers. The study was carried out in 50 patients. The result showed that CK-MB was the most sensitive and specific cardiac marker in the refraction state. 80% of the people affected from MI were male gender compare to female population in the age of less than 50 years. In our study 6 primary risk factors haven been identified with the development of atherosclerosis, CAD and MI (hyperlipidimia, diabetic mellitus, hypertension, smoking, male gender and family history) finally we conclude that the smokers (56%ge) have the higher prevalence 2-4 times than that of non-smokers. Cigarette smoking is the biggest risk factor for sudden cardiac death. Next to this hypertension (48%) diabetes (28%) and drinking too much alcohol (40%). The estimation of serum cardiac markers is essential for identifying extensive MI and reinfarction state

IP 49 Diuretic drug utilization study at a Private Corporate Hospital, Coimbatore

Nevil John Paul*,Uma Maheshwari. M and Ravi T.K.

Dept. of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore

The introduction of potent drug with an increased incidence of adverse reactions, the high cost of medications and a focus on drug use outcome have lead to the establishment of formalized drugs utilization evaluation (DUE) programs that monitor and evaluate

drug therapy. Diuretics are drugs, which increase the excretion of sodium and other ions along with water from the body by its action on the kidney. Their clinical usage evidently varies in heart failure, cirrhosis of liver with ascites, nephrotic edema, renal failure and hypertension. A prospective study was conducted at a private corporate hospital in Coimbatore for a period of eight consecutive months. 154 patients receiving diuretic therapy were identified. The author was able to observe that the dose, duration and class of diuretics varied among individuals and existing disease conditions. The most widely used class of diuretics was loop diuretics followed by potassium sparing diuretics, thiazides and osmotic diuretics. Most of the patients on diuretics were suffering from congestive heart failure and hypertension. Therapeutic guidelines for congestive heart failure were prepared and were circulated to the physicians. The results were analysed and outcome was reported to the physicians for their reference and persual. Despite the wider acceptance and significant use of diuretics in various clinical conditions which differ among individuals, the clinicians can change the management of diuretics thus improving the quality of life and overall survival of the patient.

IP 50 Misuse of Drugs

P. Praseeda*, D. Ravindra, B. Srianth, K. Umasankar & K. Hemamalini

Smt. Sarojini Ramulamma College of Pharmacy, Seshadri Nagar, Mahaboobnagar, Andhra Pradesh

Misuse of drugs can be defined as the use of drugs for purposes or conditions for which they are unsuited or even for their appropriate use, but in improper dosage. Drugs are handled by doctors, nurses, pharmacists, patients, but the maximum responsibility for paper distribution of drugs lies with pharmacist.

Misuse of drugs results from, ignorance, dependence, tolerance, altering normal physiology to enhance atheletic performance, hedonic effect, symptomatic relief, treating withdrawal symptoms.

Misuse of drugs leads to

1. Drug abuse, which is inappropriate and intentional excessive self medication of drug for non medical purposes.
2. Drug dependence, an excessive craving which develops as a result of repeated administration of the drug. It may be psychological dependence incase of psychomotor stimulant like amphetamine, hallucinogens like LSD, opates like morphine. It may be physical dependence incase of depressants like benzodiazepines, alcohol and barbiturates, opates like morphine.
3. Drug tolerance, a diminution in responsiveness, as use of drug continues. The consequence of tolerance is an increase in dose requirement. Benzodiazepines, amphetamines, cannabis, narcotic analgesics etc produce tolerance on repeated usage.
4. Adverse effects, which are unrelated to main pharmacological effect. Paracetamol hepatotoxicity, aplastic anaemia of chloramphenicol, diarrhoea of clindamicin, Amoxycillin, Teratogenicity of Phenytoin are few examples.
5. Idiosyncratic reactions which are immune mediated such as a anaphylaxis with penicillin. Many OTC products of antihistamines, antitussives, analgesics, laxatives, expectorants, deconjustants are being misused. In taking measures to prevent misuse of drugs, pharmacist should know the products which are misused and develop protocols to deal with requests for such products, train staff appropriately, be aware of implications of drug dependency treatment. Role plays on patient counseling and patient care services should be organised. Removing products of certain drugs from display, thereby allowing a sale to be easily refused for misusers.

JP 1 Development of novel teaching technology for 21st-century chemistry education

Rama Rao Nadendla

KVSR Siddhartha College of Pharmaceutical sciences, Polyclinic Road, Vijayawada-520010, A.P.

Current chemistry education has some serious problems, which prevent higher education institutions from effectively and economically training students to become qualified chemists. Various teaching methods though available for conducting regular teaching classes, we could not succeed in making our classes interesting and self-explanatory because of insufficient academic and lack of interest by students. Conventional methods have many limitations and vary from person to person.. Computer being a media, freely available to remote areas, its use for making educational program is worth for academic purposes. So far, there has been no effective, systematic and scientific chemistry teaching technology available for the chemistry. Therefore development of new powerful chemistry teaching technology is essential for the success of 21st-centrury-chemistry education. In the process of modern teaching, teachers come out of their conventional classroom chalk piece teaching to need based training in real life situations. This paper concludes with a note that pharmacy teachers and students should be given orientation course in computers and it's applications in the field of pharmaceutical chemistry. The present paper presents a flexible and efficient Chemistry Teaching technology.

JP 2 Decline of indian science and status of pharmaceutical research

Vivek Khanna*, Robby Z, Anand K, Ravindranath Shanbhag and Unnikrishnan M.K

Department of Pharmacology, College of Pharmaceutical Sciences, Manipal- 576 104.

Indian science has been on a steady decline over the past decade. In 1973, India held the 8th position in number of publications but it slipped to 15th in 2000 while China and Korea reached 9th and 16th rank respectively. Indian journals are losing their impact internationally. Only 10 out of 2000 S&T Journals published in India are accounted by SCI as compared to 30 in 1970. In 1998-1999, India awarded 10,951 PhD degrees out of which 3836 were in pure sciences. R & D expenses in India has increased from 750 to 13000 crore in duration 1980-2000. India produces more PhDs than China but fewer publications. Number of Indian patents declined from 1890 in 1989-1990 to 1881 in 1999-2000. Many such patents were of little value. We assessed the status of Pharmaceutical research as reflected by citations in International Pharmaceutical Abstracts during 1970-2003. Number of publications by top Indian Pharmacy institutions in last 5 years have been assessed. Only 2.82 per cent of total number of publications in year 2002 was from India. While number of publications from India increased in last 5 years, the quality remains low. Most publications appear in low-impact-journals without peer review. Pharmaceutical research is doing better than Indian research in a relative way. The reasons attributed are: [1]greater R & D inputs from private sector, [2]mergers in industry, [3]industry-institute interaction , [4] promotion of research by industry and educational institutions [5] increasing significance of patents.

JP 3 Restructuring pharmacology practicals at undergraduate level in pharmacy education

Ramesh K. Goyal [1], Jigna S. Shah [2], Indermeet Singh Anand [*2]

1. Department of Pharmacology, L. M. College of Pharmacy, Ahmedabad
2. Department of Pharmacology, Shri Sarvajanik Pharmacy College, Mehsana.

The status of experimental pharmacology in pharmacy institutes in India is at the cross-road. While it is felt all over to increase the emphasis on pharmacology experiments on one side, the number of experiments on animals in the departments of pharmacology for undergraduate students of the pharmacy colleges is on the decline for last couple of years. The subject of Pharmacology is gaining a sizable importance in pharmacy curriculum. At B. Pharm. level pharmacology is taught with practicals in at least two years in most pharmacy colleges, besides one year practical classes in Anatomy, Physiology and Health education.

The use of alternatives is mandatory by law as stated in Rule 17(d) of the Prevention of Cruelty to Animals Act, 1960. In this regard PCI through its letter No. 10-1/2002-PCi-16593-17122 dated 7/6/2003 and CPCSEA through its letter No.CPCSEA/CH/ORG/ Pharm/2003 dated 18/6/2003, has directed all approved institutions conducting diploma/degree courses in pharmacy to use Ex-Pharm Blank CD developed by JIPMER Pondicherry. This is a welcome step which would reduce the use of laboratory animals. Many universities throughout India have proposed/prescribed the use of alternatives wherever available.

Pharmaceutical Education is witnessing a remarkable change in present scenario with the introduction of information technology. Many other Computer Assisted Learning (CAL) softwares/ simulators are available which can be used as alternatives for other experiments also.

The authors feel that to streamline pharmacology practical syllabus it is the ultimate requirement not only to update it but also to enforce a uniform syllabus for pharmacology practicals throughout India.

The authors propose:

- Such CAL softwares can be identified by the AICTE / PCI and could be prescribed to all pharmacy institutes through out India.
- A list of all possible experiments which can be conducted should be published by AICTE / PCI.
- Remolding of undesired experiments.

Establishment of Simulated Pharmacology laboratories with audio / Video / Computer aided teaching facilities.

JP$_4$ Pharmaco-economic Practices: A key of survival

N.H. Indurwade*, S.B. Kosalge, V.V. Redasani S.S. Chavan

S.N. Institute of Pharmacy, Pusad-445 204, Dist. Yavatmal (M.S.)

Pharmacy is one of the crucial area in the science and development and thus it involves the high laboratory infrastructure overall. The laboratories involved should be with highly sophisticated instrument and basic needs, to carry out the research as well as basic practical work. Pharmacy institution, whether it is government aided or run by private management are going through a lot of financial crisis nowadays and economics of the laboratories is one of the major problem being faced by the institutions. The aim of the present study is to make aware the pharmacy institution about impact of financial crisis help to solve it. The laboratory setups play a crucial role in basic installation of pharmacy institution. The aim of the present study/ survey is to make aware the pharmacy institution about impact of financial crisis help to solve it.

An annual record was maintained and methods were adopted in some of the laboratories in our institution and comparative study was carried out with past record and result was interpreted. Economy involved in laboratory accessories, economy with utilization of newer techniques, symbiotic relationships in between laboratories.

It is obvious from experiment that the methods will reduce the running cost of the laboratories with 12% to achieve overall minimization from financial crisis of institutes and sober laboratories economics, the above cited examples will set up a mile stone and if properly handled could help to stand up the institution from the hazard of financial crisis.

JP$_5$ Should "Drug metabolism- an important tool for drug design" be a part of pharmacy curriculum?

S. V. Bhandari * [a], A. B. Shirode, L. A. Deshmukh. N.S.Vyawahare, S.V. Gandhi.

AISSMS College of Pharmacy, Near RTO, Kennedy Road, Pune 411 001.

Drug metabolism, drug design, pharmacy curriculum

After the success of structure-based drug design and mechanism-based drug design, now metabolism-based drug designing seems to be booming and making its impact on process of drug discovery. A growing awareness of key role that drug metabolism plays as determinant of *in vivo* drug action has led many companies to include examination of drug metabolism properties as part of their screening processes in selection of drug candidates. Consequently, industrial drug metabolism scientists have emerged from their traditional supportive role in drug development to provide valuable support in drug discovery efforts. With a better understanding of fate of drugs, a balanced *in vivo / in vitro* approach and intelligent application of sound principles in pharmacology and enzymology, the drug metabolism scientists can contribute significantly to the discovery of safer and more efficacious drugs.

Unfortunately, this major section has never been given due attention either in graduate or post graduate pharmacy curriculum across India. In the present paper, the importance, different techniques to improve i) selectivity of action ii) potency iii) physicochemical properties and thus biological activity of a drug, to reduce drug toxicity and time required for its screening, minor and major details of metabolism related new drug design, its scope are discussed with numerous examples. Our aim is to highlight the importance of this neglected part and bring it to the attention of pharmacy fraternity, so that, taking into consideration its scope and contribution with vast array of application to drug discovery, metabolism studies will be stressed and introduced as a special subject in the pharmacy curriculum.

JP$_6$ Information technology and pharmacy development go hand in hand

M.K.Anil Kumar*, V.Anand Kumar, E.Shyam Prasad, M.A.Nadeem, K.Vivek

Smt.Sarojini Ramulamma College of Pharmacy Mahabubnagar, Andhra Pradesh - 509001.

Modern information technologies and world wide communications through the internet play a significant

role in pharmaceutical research across the globe. The world wide web can be intimidating place to locate accurate information of the drug. As an impact of pharma informatics a new concept of on line continuing education programme came into picture where in one can continually update himself/herself while sitting at home of office, by participating in online discussion programmes related to the subject of their interest.

The ARPANET provide a test-bed for networking research and development. The other significant events include the introduction of the desktop computers, the development of networking tools such as telnet, FTP, Gophers and www and the release of graphical browsers. NSFNET to upgrade its speed several time. Major currently academic and commercial molecular software systems such as AMBER, GRID, CHEM-X, EMBED, FRODO, GROMOS, IDAS, MOGLI, TRIPOS,DISMAN AND CONCORO etc are developed in different organization which are very helpful in drug designing.

Compilation of important websites will stimulate and instruct researches those who are involved in pharmaceutical research. The list of websites that will be provided in this presentation is expected to facilitate their search.

JP$_7$ Need for the introduction of pharmacogenomics in pharmacy curriculum

G. Subramanian, S. Mutalik, S. Agrawal, R. Karki and N. Udupa*

College of Pharmaceutical Sciences, MAHE, Manipal 576119, Karnataka

The markets for the traditional output of schools of pharmacy, namely education, research and graduates, are changing. The pharmaceutical industry is moving fast to become more efficient, under pressure from overly costly drug development. The development of safe and effective new therapeutics is a long, difficult, and expensive process. Pharmaceutical education has to set new priorities to keep pace with the challenges related to genomic technologies for the personalized medicine in post genome era. The development of new initiative education programs, for both undergraduate and postgraduate curricula, in pharmacy has to be focused on preparing pharmacists oriented for both pharmacy practice and drug research and development. This can be achieved by providing future pharmacists with knowledge, skills and attitudes to be more competitive in the health care system, pharmacy practice-related fields, pharmaceutical industry and drug research and development areas, or finally in academia. Educators and pharmacy colleges have the responsibility in preparing students to familiar with latest developments in pharmacogenomics and medical bioinformatics for better patient care and cost reduction in the drug development process. The curriculum in Pharmacogenomics, learning sources and the ethical aspects of incorporation of subject are dealt in this article.

JP$_8$ Computer aided multimedia presentations: An alternative to the traditional classroom lecture

Sunil Agrawal, Srinivas Muthalik, G. Subramanian, Roopa Karki and N. Udupa*

College of Pharmaceutical Sciences, MAHE, Manipal

Traditional teaching strategies, though useful for the dissemination of information, especially to a large number of students, can promote passive learning and can become monotonous. Therefore, innovative educational methods can become important tools for empowering students to learn and retain presented materials. This paper describes an alternative approach to the traditional classroom lecture, which was implemented with first year postgraduate (Pharmaceutical Marketing branch) pharmacy students. This nontraditional approach consisted of the development and deliberations of a topic in the form of PowerPoint presentations. Students were divided into teams of two and each team was given a one hour time period to present their project during which their classmates and faculty members asked questions. Overall, student acceptance of this sort of presentation was positive. From the faculty's perspective, the PowerPoint presentation is a fun and efficient way to promote learning and thinking skills in pharmacy students. It presents students with the opportunity to be creative and to develop useful presentation skills. This presentation also promotes professional communication and moves students out of passive learning into active learning roles.

JP$_9$ Use of over head projector (OHP) in regular teaching classes

Munish Garg*, Chanchal Garg

L.S.F. College of Pharmacy, Moga, Punjab - 142001

The use of Over Head Projector (OHP) should be encouraged in regular theory and practical classes in the Pharmaceutical Institutions which is still limited to a few Institutions. Not only it is less time consuming but also results in better understanding for the students and efficient teaching for a teacher. In this context, we had conducted an experiment in which we had chosen students of B.Pharm 2nd semester, 4th semester and 6th semester. Two topics from their routine syllabus were selected from each class in such a manner that they required almost similar attention and caliber. One topic was taught by conventional method by taking lectures with OHP whereas, second topic was taught by using

OHP. After delivering the lectures students were asked to take an examination without any prior intimation. The question paper carried multiple choice questions short answer type questions and long answers type questions. A viva was also conducted from the same topics. The average % marks were calculated after evaluation of theory examination and grades were awarded for viva. The results reveals that students were able to score 25% more marks in theory and also got better grades through OHP teaching method as compare to the conventional method of teaching.

JP$_{10}$ Status of solid dispersion technology research: A survey

Vijaya Kumar S.G.[1], Singh S.K.[2], Parveen Goyal[3], Ajit Singh[4] and Mishra D.N.[2]

1. Sanjivani College of Pharmaceutical Sciences, Rajota Khetri, Rajasthan-333 503.
2. Faculty of Pharmaceutical Sciences, Guru Jambheshwar University, Hisar-125 001.
3. Lord Shiva College of Pharmacy, Sirsa- 125 055
4. Government Institute of Management and Pharmacy, Adampur, Haryana.

Solid dispersion is a unique technology, which is being extensively used for increasing the solubility of poorly mater soluble drugs. Same technology is used for desiring sustained/ controlled release products in highly mater soluble drugs. The technique is also applicable for improving the stability. Compatibility and organoleptic properties of drugs and formulations. A detailed survey on international status of solid dispersion technology had been done for the last 20 years through Medline and other journals. It was found that various methods of solid dispersion Viz. Melt method, solvent method, complex formation co-grinding, kneading mixture, swollen carrier mixture, freeze drying, spray drying. Twin-screw extrudation, solution-enhanced dispersion with super critical fluids (SEDS), milling, compaction and ultrasound compaction had been employed. It was found that NSAID's are the most widely used drugs for solid dispersion. Apart from this antimicrobial and cardiavasular drugs are also used. In carriers, poly viny pyrrolidione, polyethylene glycol and cyclodextrins are commonly employed. In recent past alteast one article related to solid dispersion were published in every issue of journals like. Journal of pharmaceutical sciences, International journal of pharmaceutics, Drug Development and Industrial pharmacy, Indian Journal of Pharmaceutical Sciences. The Survey also highlights the list of suitable drug candidates, polymers, formulation techniques and marketed products for solid Dispersion.

JP$_{11}$ Survey on molecular dispersion technique and its international status

Ravichandran, M., Ajey Reddy, T*, Manikandan, S.R., Praveen Kumar, C.D. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu- 643001.

Molecular dispersion technique is a unique approach for presenting a poorly soluble drug in an extremely fine state of subdivision to the gastrointestinal tract and there by increasing the oral bioavailability. A survey consisting of about 20 years of data from International Pharmaceutical Abstracts was therefore made to understand the developments and the status of solid dispersion technique. In this survey, solid dispersion research articles were categorized on the basis of drugs, carriers used, publication sources, and the countries involved in the research. The data's available are compared and developments are presented. Indomethacin followed by griseofulvin was extensively employed in the formulation of solid dispersions. It was observed that drugs belong to categories of NSAIDs and antifungals have been widely reported. Polyethylene glycol 6000 is the largely used polymer. Solid dispersions have been reported extensively in Drug Development and Industrial Pharmacy and multiple publications were observed in International Journal of Pharmaceutics, Journal of Pharmaceutical Sciences, and Eastern Pharmacist. Researchers from India have contributed maximum number of articles followed by Egypt, Japan and United States of America.

JP$_{12}$ Prevention of SARS : Role of Pharmacist

Vikas, Meenakshi Bharkatiya*, Y.S. Tanwar, R.K. Nema, G.D. Gupta

B.N. College of Pharmacy, Udaipur- 313002. (Raj.)

SARS which is an epidemic disease has given a new threat to the whole world. It is a respiratory illness that has recently been reported in Asia, North America, and Europe. Approximately 5050 people have been infected by SARS and 321 deaths have been reported from 26 countries. Deaths have been reported in Hongkong, Vietnam, Singapore, Thailand, Canada and China. Recently SARS patients have also been identified in India. Scientists are not yet certain what pathogen is behind the disease. Recently CDC scientist said the disease may be caused by Corona virus that can cause common cold. It has a crown like appearance and associated with respiratory, gastrointestinal and liver diseases. Others have found signs of Paramyxovirus which cause measles, mumps and other diseases. SARS appears to be transmitted by droplet transmission.

The symptoms of SARS like fever of over 38° C, headache, dry nonproductive cough, decreased WBC count, diarrhoea, difficulty in breathing are common to a number of well known diseases but the WHO is concerned because of several reasons. The virus is believed to be a more lethal form of Corona virus. Usual medications like antibiotics and antiviral drugs do not respond to the disease. The rate at which the disease is spreading and the virus causes serious Pneumonia. SARS effect to the economy of the whole country like traveling, tourism and business is affected.

In the present study it was found that SARS is a very dangerous disease and also challenge to researchers to develop antibiotics/vaccines or any other dosage form to prevent SARS.

JP 13 International status on implantable therapeutic systems: A survey

Ravichandran, M., Jeeva Elizabeth Sam*, Manikandan, S.R., Praveen Kumar, C.D. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamil Nadu 643 001

Implantable therapeutic systems are used for long term and sustained drug administration of drugs belongs to steroid harmones. For better control of drug release, rate controlling biodegradable and non-biodegradable polymers are used. A survey consisting of about 30 years of data from International Pharmaceutical Abstracts was therefore made to understand the developments and the status of implantable drug delivery research. In this survey, implants research articles are categorized on the basis of drugs, polymers, delivery approaches, research resources with implantable drug delivery articles and also the countries, which have contributed for the same. The data's available are compared and developments are presented. Drugs belong to category of steroid hormones have been extensively reported followed by corticosteroids and NSAIDs. Poly epsilon-caprolactone have been widely employed in the formulation of implants followed by Polylactide co-glycolide and Polymethyl methacrylate. *In vivo* studies are performed in human subjects and patients. Reports on patient studies are more when compared with that of human studies. Animal models such as rats, pigs, mices, rabbits and dogs were employed to perform *in vivo* studies. Implants have been extensively published in Journal of Controlled Release, followed by International Journal of Pharmaceutics and Contraception. Researchers from U.S.A have contributed extensively in this research area followed by researchers from U.K, India, Japan and Germany. It is concluded that this survey is therefore, highly useful for industries and scientists, who are involved in designing implantable drug delivery system.

JP 14 A survey on nanoparticle drug delivery research and its international status

Ravichandran, M., Ambika, P*, Manikandan, S.R., Praveen Kumar, C.D. and Suresh B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ooty, Tamilnadu 643001

Nanoparticular drug delivery approach provides a more predictable targeting of a drug with decreased toxicity, controlled release and protection of drug against the environment. It gives greater convenience and better patient compliance. A survey consisting of about 30 years of data from International Pharmaceutical Abstracts was therefore made to understand the developments and the status of nanoparticular drug delivery research. In this survey, nanoparticles research articles were categorized on the basis of drug delivery approaches, drugs, polymers used, evaluation techniques, publication sources and the countries involved in the research. The data's available are compared and developments are presented. It was observed that anticancer drugs have been extensively used and followed by CNS, CVS, antibacterials, NSAIDs and corticosteroids. Poly-dl-lactide co-glycolide has been extensively used for the preparation of nanoparticles. Scientific journals namely International Journal of Pharmaceutics, Journal of Controlled Release, Pharmaceutical Research, and European Journal of Pharmaceutics and Biopharmaceutics. Researchers from France had contributed extensively for the development of nanoparticles followed by Germany, U.S.A, Spain, and Japan. It is concluded that the present survey is highly useful for pharmaceutical industries and scientist, who are involved in nanoparticular research.

JP 15 Thalassaemia, awareness, prevention care and control in the new millennium

Kamble Sagar B*, Velingkar V.S., Modhave Yogesh S, Shaikh A.R

K.M.Kundnani College of Pharmacy, 47, Dr. R.G. Thadani Marg, Worli Sea Face, Mumbai 400018.

Thalassaemia is one of the commonest single-gene disorders known. Although first described in 1925 by Cooley and Lee, real progress in understanding the pathophysiology and molecular biology of Thalassaemia has occurred in the last few decades, leading to new approaches in the diagnosis and management of the disorder.

Advances in the therapy, including blood component transfusion, effective chelation and bone marrow transplantation, have improved the quality of life of Thalassaemia.However, as therapy of Thalassaemia is expensive and beyond the reach of

many patients, a national awareness programme is needed for prevention: Screening high risk populations, proper counseling and antenatal testing.

It is estimated that 35 million people are affected in our country and 10,000 -12,000 children with Thalassaemia major, are born every year in India .The majority of these children succumb to this disorder in the first decade of their life because of undiagnosis or lack of proper treatment and poor medical facilities.

This presentation is putting a serious attempt to make people aware about,

1) What is Thalassaemia? 2) Prevention of Thalassaemia.3) Diagnosis and treatment of Thalassaemia.

- A broad survey was done in five districts for the awareness, prevention, care and control about this disorder.
- The districts selected for this purpose were four corners of Maharashtra state viz; Mumbai, Pune, Nasik, Kolhapur and Satara.
- The people selected for the survey were grouped into various categories like Students, Businessmen, Govt. and Private employees, Medical Practioners some Social workers and others.
- Their awareness and opinions about this disorder were recorded and data generated showed the statistical significance.

Results and Discussion: The experimental work performed in the form of a broad survey shows the following results based on dialogue and discussion with the people in different categories of various districts in the state of Maharashtra.

1) Survey in Mumbai: 80.23% (Unaware) — 19.76% (Aware)
2) Survey in Pune: 90.13% (Unaware) — 9.86% (Aware)
3) Survey in Nashik: 96.25% (Unaware) —— 3.75% (Aware)
4) Survey in Satara: 99% (Unaware) —— 1% (Aware)
5) Survey in Kolhapur: 95.08% (Unaware) — 4.91% (Aware)

Summary and conclusion:

1) A broad survey was done in five different districts of the state of Maharashtra; various categories of the people were selected for such type of survey and their opinions and suggestions were recorded.
2) Stastical data generated from above survey shows that 92.13 % of people were unaware about this disorder in State of Maharashtra.
3) This type of work is a need of the day, for awareness, care and control of such disorder, was the concluding opinion of the majority of the people.
4) The diagnostic facilities for this disorder are not easily available in the majority of the places of survey.

Therefore a need arises to present and discuss this topic on a national level platform like IPC 55th.

JP 16 Pharmacy education at cross road - challenges ahead

S. Balasubramanian

A.K. College of Pharmacy, Krishnankoil 626 190

Today world health scenario has thrown a challenge to us. The challenge is for accepting a major role in the Indian health care system i.e. to shoulder clinical pharmacy services. The concept of clinical pharmacy has dawned into the profession some 30 years back in developed countries. We are yet to wake up! What is the reason? How to go about it?

We are ill equipped to meet the challenge and that is why we are not even demanding its implementation in Indian hospitals. Revolutionizing pharmacy curriculum is the need of the hour. As of how, pharmacy education in India is a heterogeneous mixture of industrial and clinical subjects. They should be separated and two streams of B. Pharm (Industrial) and B. Pharm (Clinical) should be started.

Pharmaceutical science has developed enormously in the last 50 years, instead of mastering and specializing in those developments; we try to stuff all those new things into the existing setup. As a result, a B.Pharm graduate is master in none. Whenever science develops, separation and specialization of the new areas is the right way to choose. It is long over due in our pharmacy curriculum.

Some may argue, specialization at PG. (M. Pharm) will do. That argument holds good only when the UG subject matter is less. Clinical subjects are so vast that without proper foundation you cannot just build upstairs. Look at the engineering courses (B.E.). New subjects are not stuffed in the existing B.E. syllabus. Apart from traditional civil, mechanical and electrical branches many specializations like electronics, communication, computer science, information technology, biotechnology and medical physics are added to it, in the recent past. One more example is the B.D.S. course - an undergraduate level specialization - bifurcated from medicine syllabus. Hence we should not allow our pharmacy education to be stagnant and rotten. We should make it a dynamic science similar to that of engineering.

Since we are sleeping, others are overtaking, the starting of new courses by many universities infiltering into our area, are the proof for it. If the conservatives are still reluctant for bifurcation, let there be single B.Pharm. course, but let us introduce specialization at least after first year as in engineering.

It is time to awake, arise and acheive!

JP 17 Teaching pharmaceutical practice broad related in literacy & poverty

Vikas Sharma*, Sandeep Jatav, Naresh Sharma, Arvind Saraswat, Rakesh Jangid, A.K. Shrivastava

B.N. College of Pharmacy, Udaipur, (Rajasthan) 313001

Teaching of Pharmaceutical Practice is completely western orientation. We do wish to serve Indian mankind with the help of experience of western mood & therefore our teaching is ill directed and unfold full.

It has been observed that the trained Pharmacist are unable to survive in the competition with the graduate of other field entered in market illegally serving as proxy pharmacist until unless they bow around the prevailing malpractice of trade world.

Therefore the author wishes to suggest some modification in the pharmaceutical practice teaching to cater the actual need of India.

Problem Of Present System Verse Need :

1. Literacy :

   If you do not have education, you cannot have trained people in health care; you can't have a legal system that works; you do not have education that provide ethical values; if you do not have education then you are paralysed to construct any industry, road etc.

   Some two-thirds of illiterate adult in the Asia-Pacific region are in India & Nepal.

JP 18 Pharmrceutical impurities - A mini review of ICH guidelines

A. D. Deshpande, V. V. Potnis, A. G. Chopade*, A. B. Kute.

Padmashree Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune -18

The control of pharmaceutical impurities is currently a critical issue to the pharmaceutical industry. The international conference on harmonization (ICH) has formulated a workable guideline regarding the control of impurities

Impurities in pharmaceuticals are the unwanted chemicals that remain with active pharmaceutical ingredients (APIs), or develop during the formulation, or upon aging of both API and formulated APIs to medicines. The presence of these unwanted chemicals even in small amounts may influence the efficacy and safety of the pharmaceutical products.

Impurities in new drug substances are addressed from two perspectives:

Chemical Aspects includes classification and identification of impurities, report generation, setting specifications, and brief discussion of analytical procedures; and,

Safety Aspects includes specific guidance for qualifying impurities which were not present in batches of new drug substance used in and clinical studies and/or impurity levels substantially higher than in those batches. Threshold limits are defined, below which, qualification is not needed.

Impurity profiling (i.e. the identity as well as the quantity of impurity in the pharmaceuticals) is now receiving important critical attention from regulatory authorities. The different pharmacopoeias such as the British Pharmacopoeia (BP) and United State Pharmacopoeia (USP) slowly incorporating limits to allowable level of impurities present in APIs or formulations. Many impurities which commonly present in pharmaceuticals can prove to be toxic to human life or can enhance the degradation of the active ingredient. Hence detailed profile of such impurities needs to be prepared.

The present article makes an attempt to provide an insight to this issue and quotes some examples of impurities is commonly used in active pharmaceuticals. Also it discusses the various sources of impurities, classes of impurities, degradation pathways of some drugs which lead to generation of metabolites which can act as impurities. The concern is more now for specifying the biological safety of an individual impurity or given impurity profile level specified as per ICH guidelines.

JP 19 An innovative approach for quality improvement of industrial pharmacy in pharmaceutical education

Kumud Padhee*, Satyanarayan Pattnaik, B. Mahanti, P. Suresh

College of Pharmaceutical Sciences, Mohuda, Berhampur - 2, Orissa

Pharmacy education in Indian context is turned towards industrial pharmacy. A major component of the curriculum is inclined towards aspects related to industry. The educational institutions in India being separate entities with no industrial attachment of its

own, the majority of students from such institutions forced to visit pharmaceutical industries as a part of course work to get a practical exposure on the concept of their institutional learning process.

In the present investigation an attempt has been made to study the need for institutionally based industry set up and to study all possible practical aspects in materializing this concept. In the complex system of the provisions of schedule M to the Drug and Cosmetic rule 1945 and relevant provisions of import manufacture and sale of drug as applicable in the Drug & Cosmetic act 1940 and rules made there under in 1945 and in the context of stringent provisions of education regulation / norms and standards for pharmacy education in Indian context need to be carefully assessed. The sample survey was conducted in identified groups like Pharmacy Students, Academicians, Industrial Experts, Enforcement Officials, Statutory Bodies etc. The information so generated was compiled and computed.

The study reveals that in order to effectively handle the subject of industrial pharmacy with desired practical exposure there is a need for a modern pilot plant in the institutional set up. The concept can further be expanded with financial viability for establishment of the institution based industry as an individual unit which can cater the needs of drug market besides promoting the causes for augmenting institutional efforts for the quality improvement of industrial pharmacy in the pharmacy curriculum. The details shall be discussed.

JP 21 Need for a uniform syllabus In P.G level

P. R. K. Murty*, Satyanarayan Pattnaik, Kumud Padhee, V. Sumant Reddy, P. Ghosh & P. Suresh

College of Pharmaceutical Sciences, Mohuda, Berhampur - 2, (GM)

The introduction of GATT has opened up world market in all technical fields possessing a challenge for present Indian educational system requiring radical reformation strategies to meet the international expectations. Pharmacy being one of the frontline technical courses under the AICTE Act, 1987, with tremendous manifold potential in various fields like drug production, Pharmacy education, Pharmacy practice etc, needs necessary up-gradation to meet the expected standards of international accreditation. In the light of the above challenges the present structure of pharmacy education need to be reviewed so as to redesign the structure. The duration of the P.G program in pharmacy, the nature & subjects to be covered, the nature of the project work to be undertaken at the P.G. level are to be properly calibrated so as to make the end product acceptable to international market.

A sample study of the pattern of M. Pharm program offered by various leading Pharmaceutical Institutions & Universities in India vis-a-vis the pattern adopted at the international level reveals that there is a lack of uniformity of the course structure. The resent landmark decision of AICTE, establishing uniform national standard for the duration of the course is regulated for all institutions in India is a welcoming step in the path of reformation. The structure of the M. Pharm program for each specialization as suggested by AICTE vis-a-vis the existing course structure adopted by different universities in India were compared .To supplement the data, sample survey was conducted among identified peer groups to draw their expert opinion on the pattern of course structure.

The study reveals that the present 4 Semester M. Pharm course need to be properly restructured. In the suggested module the 1st Semester is common for all specializations with subjects representing the core branches of pharmacy specialization. The 2nd Semester is to be targeted towards a specialized area incorporating need based advanced subjects in relevant specializations. In order to improve the professional skill regular seminar presentations are suggested at 1st & 2nd semester, which includes covering of ground work for the project work. The 3rd & 4th Semester are to be dedicated for project work. The details shall be discussed.

JP 22 Bioinformatics - A opportunistic profession to pharma graduates

N.C. Kumar, S. Dhanalakshmi, S. Amarnath, M.D. Raja, M. Sugumaran* and V. Ravichandran

Pallavan Pharmacy College, Kanchipuram ,T.N

The present paper is based on objective to expose and make awareness in pharma graduates to newer way of opportunity through bioinformatics profession.

Bioinformatics can be defined as " The mathematical, statistical and computing methods that aim to solve biological problems using DNA and amino acid sequences & related information".

The science of bioinformatics deals not just with sequencing techniques but having application in frontline areas such as drug design, gene therapy, diagnostics, new markers for diseases, vaccines and biochemical processes.

There has been a sudden spurt in the demand of such professionals by gene - hunting companies. Pharmaceutical companies are now seeing real value in gene mapping and sequence data and have started attracting experts from academia. Major pharmaceutical and Biotechnology companies (Dr.Reddy's Laboratories, Nicholas primal, MBT, TCS, DSQ Biotech.) have setup large R & D groups in Bioinformatics.

Bioinformatics course is available at various private organization and Government Institutions. Information about this course get on internet at different websites.

Pharmacy graduates have golden role in this profession because of their brief knowledge in biology, anatomy, physiology, pharmacology, biochemistry, microbiology and biotechnology etc., during their curriculum.

JP 23 Criteria of M.Pharm. Admission: GATE or combination of GATE and B.Pharm.

Ketan Ranch*, Akshay Koli, J.S. Shete, M.P. Wagh, N.N. Inamdar

N.D.M.V.P. Samaj's College of Pharmacy, Gangapur Road, Nashik - 2.

As per article 1.3 of GATS, Govt. services like educations that are not meant for commercial purpose can be included in GATS (General Agreement on Trade in Services). In order to face the challenge of globalization of education, the present education testing services like GATE, CAT, IT-JEE, NET and others must be upgraded and to be modernized.

In the present work an attempt has been made to compare the performance of the student in university B.Pharm examination with their performance in GATE examination. The total 338 students from 15 different universities from all over India were selected for the present study. Their percentage marks in B.Pharm were correlated with their GATE percentile scores. From statistical analysis an attempt was made to compare the degree of correlation between the two examination performances of different universities.

Out of the 15 universities, significant correlation between performance in university B.Pharm exam and GATE exam was found only in 4 universities. The universities were further categorized into the following categories.

1. Pune University
2. Universities in Maharashtra other than Pune University
3. Universities outside Maharashtra.

In the three categories, significant correlation was found only in Pune University. From the above observation it is very clear that the performance of student s from different universities cannot be considered as basis for comparison. It is injustice to students to be compared on the basis of B.Pharm marks as per current admission criterium of 70:30 combination (GATE:B.Pharm).

The course of M.Pharm where student has to carry out research should be the one who can understand the problem, can think over the possibilities of solving it in available conditions should be judged by the better criterion of the objective questions. Thus the GATE exam of such objective pattern seems to be the wiser basis of judging and admitting the student for M.Pharm. Again GATE examination score emerges as more logical criterium.

JP 24 Optimal design of experiments in instrumental analysis in the wake of harmonization of the pharmacopoeial methods and rationalization of the same for undergraduate students

Visalakshi Chivukula* and A.Raghu Ram Rao

Medicinal Chemistry Research Division, University College of Pharmaceutical Sciences, Kakatiya University, Vidyaranyapuri, Warangal 506 009, AP, India.

Harmonization of the pharmacopoeial methods of analysis of typical drugs makes it highly imperative to educate and train students at undergraduate level about practical and official methods of carrying out instrumental analysis. Experiments designed for the students should aim at providing an insight into the various aspects of analysis, handling of instruments, developing technical skills and ability to search, comprehend and practice the official methods available for assay of typical drug substances. Practical training of the students should be fabricated to suit the industry requirements and official stipulations rather than being theoretical.

Some official assays were selected from the latest editions of USP-NF, BP and IP and experiments were carried out our Pharmaceutical analysis laboratory. The results were encouraging and they complied with the recent trends in the harmonization of pharmacopoeial standards. Drug entities selected include antibiotics, vitamins, hormones, sulpha drugs, barbiturates, organomercurials etc

JP 25 Challenges and changing roles of pharmaceutical Journals: electronic reprints and e-papers

Mueen Ahmed K.K[1] and Aisha Khanum[2*]

1. Dept. of Pharmacognosy Al-Ameen College of Pharmacy, Bangalore
2. Dept. of Pharmaceutics Al-Ameen College of Pharmacy, Bangalore

The rapid adoption of internet accessible resources has resulted in an exponential growth in the

variety and type of information resources. Online journals play an important and efficient tool in systematic literature search and provide researchers access to achieve journals online. E-papers has fostered active research and development directed toward locating data that are appropriate to answer specific queries. This paper continues with a discussion of importance and usage of online journals which has become increasingly significant in pharmaceutical research. This article is expected to educate, update academicians, researchers involved in drug discovery.

JP 26 Fun Teaching: A Positive Outlook

Pirthi Pal Singh*, Shah Kumar A., Patravale Vandana B.

Pharmaceutical Division, University Institute of Chemical Technology, University of Mumbai, Matunga, Mumbai. 400 019

"Change" is the law of nature. The inevitability of change is expressed in many ways: the cycle of season, the growth of children and in folk expression which range from the elegance of Heraclites "you cannot step in the same river twice". Today is the era of renaissance. The phenomenon has crept into all the fields be it entertainment, technology, marketing or may be the admission procedure to the academic institutes. The new buzz word of the millennium is "change" - a change from the old traditions without abandoning them. So, why should the pharmacy education be left behind? The time has come where the teaching style has to be changed from its current traditional approach to the modern "Fun Teaching". The same thing can be expressed in many ways viz., verbally, visually or by actions and emotions. It is well known that what we see remains in our memory for a longer time than what we hear. Thus a visual demonstration is far more effective as compared to a verbal communication. Cartoon pictures or technical models help students to understand the concepts in a better way. Imagination of a teacher is the limit in fun teaching. One can even correlate a fluid to a shark or NMR to a village. The advantages of fun teaching are numerous including clear understanding of the subject matter, ability to grasp difficult topics and reduction of mental stress.

JP 27 Impacts of WTO - Perspectives in pharmacy education

V.A. Patel, N.P. Chotai, S.S. Pandya, B.G. Patel, D.M. Modi, N.B. Joshi*

A.R. College & G.H. Patel Institute of Pharmacy, Vallabh Vidyanagar - 388120 (Gujarat)

General agreement on the Trade in Services (GATS) becoming fully operated by 2005, any institutions from WTO member country will have to trade in education in India and vice versa. Foreign universities will compete in the growing higher education market with courses which are flexible and market related in big way after 2005.

India, being a signatory to WTO has to gear up for its implications beyond the year 2005. Pharmaceutical sector getting great influence of WTO and GATS in its different professional avenues. With the implementations of the WTO proposals on intellectual property rights, Indian companies will have to increase their focus on research and development of new medicines. Pharmacy education in India has never got much influence from other countries till date. Instead since long, pharmacy graduates and professionals from India had experienced outward drain to foreign countries. In the light of above facts the basic objective of this paper is to highlight the impacts of WTO on higher education in general and pharmacy education in particular.

The WTO has identified four main modes of trade in education namely (a) cross boarder supply (b) consumption abroad (c) commercial presence (d) movement of natural persons. It may be noted that IGNOU has started offering various courses through distance mode. AICTE has already geared up to regulate this and other possible trade practices. The deliberations and discussion on different modes per se may help to exchange the views on globalization of pharmacy education leading to the new horizon.

JP 28 Need of a Job-based reorientation of B.Pharmacy syllabus including defense ervices

Samanta, M.K., Yashwant Dhanorkar, Rajesh Kumar*, Atul Daroi and B. Suresh

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund 643 001

The present prospective job opportunities available for B. Pharmacy students are in production and Quality control areas, administration and management, marketing research and development, medical detailing departments of pharmaceutical industry in hospital and in teaching. The present B. Pharmacy syllabus in most of Indian universities aim to produce a graduate who is a jack of all trades but master of none. The students have to study compulsory all subjects through it is no useful for his job placement. So there should be reorientation of syllabus according to specialization and job - oriented reconstruction of syllabus. There should be specialization oriented change in B. Pharm syllabus, according to present need of Pharmacist. It should be classified as - Industrial Pharmacist, Hospital Pharmacist, Research Pharmacist, Retail Pharmacist, and Government Jobs and in Defense Services. For Govt. Jobs and in Defense Services there should be a nationalized level exam for entry of pharmacist and

scrutiny should be on the basis of merit strictly. There should be special posts and IAS and IPS level for controlling drug abuses more efficiently as they are from pharmacy field only. There should be specialized syllabus for defense services. For that a 4 year extensive training to students should be given with disciplined, punctuality, motivation, steady schedule, physical fitness, mental fitness, health camps and social health services. These students should be preferred for later on for further defense R&D also for preparing biological warfare to strengthen the nation's position in security &defense. Thus, the new course offers the advantage that the graduates would be highly trained in their respective fields and would therefore be more suited to their jobs.

JP 29 Positive steps towards globalization of pharmacy education

Palaskar G.S., Gupta P.*, Zambad S.P., Ghaisas M.M., Deshpande A.D., Dept. of Pharmacology

Padm. Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune - 411 018.

An important debate is currently taking place within universities, researchers, diplomats and governmental sectors all over the world: can education be considered as a commercial service and, consequently, should the world trade organization (WTO) regulate it?

WTO secretariat, in September 1998, after mentioning that rapid changes in the area of higher education, observed that "education also exists as a 'Private constitution' item with a price determined freely by the providing institutes". They added that the "consequences of this shift in control have included less government funds, and more competition and institutional reforms to cut costs and raise revenues. These, in turn, have resulted in an effort to attract more fee paying students, including foreign ones".

In present discussion the idea of a positive agenda applicable to pharmaceutical education is suggested. The principles adopted by the 5,000 participants at the world conference on higher education, which are perceived in many countries as the guidelines for concrete action & reforms in the field of pharmacy education are mentioned. Some points to be adopted to globalize the pharmaceutical education, such as 1) Higher education should be considered as a public service, 2) while diversified sources of funding, private and public 3) is necessary public support for education and research, are suggested higher. Positive steps to improve the pharmaceutical education must serve sustainable development and must help to build a better society or, as it would be said today, to build a fair globalization, which all societies in the world deserve.

JP 30 Barriers to industry - academia collaboration - an investigation

M. Pavan Kumar, Y. Madhusudan Rao, V. Rajesh and A.K. Radha Devi*

University College of Pharmaceutical Sciences, Kakatiya University, Warangal

Indian pharmaceutical industry has been subject to various changes of late. These may be attributed to the advances in science and technology and the need to survive in a globalised environment. In the last decade, there has been manifold expansion in the RD set ups and more revenue spending on research has been noticed from Indian pharma companies. Many efforts have been put and much has been spoken by different pharmaceutical organisations including academia, industry and government bodies since a decade in collaborative research, but little progress has been made in this direction.

The basic objective of the present paper was to investigate the reasons for slow progress in collaborations, identifying the barriers and come out with suggestions regarding the deficiencies observed. The views of academia and industry on each other go hayward and also each have unmatchable expectations, added to this are barriers between the two. On the basis of investigations and findings from academia and industry on some of the ongoing tie-ups, completed and dropped projects and also on the hurdles for the new collaborations in pipeline, a fer of the most common barriers identified in the study were as follows. 1) Lack of trust and confidence on each other 2) Modalities, Expectations and Terms of collaboration was not clearly specified at tea time of agreement. **Example:** In one case, collaboration terminated, as the objective was not clearly spell at the time of agreement. Academia submitted data indicating the increase in bioavailabity of drug X from 20% to 60% and the industry refused to accept the results, since their expectations was to increase upto 80% bioavailability. 3) Agreement and execution of collaborative work carried out separately by different individuals on respective sides leading to complications and unclear objectives 4) Industry expectations and academic expectations often do not match 5) Industry policies often change 6) Person in charge of research work gets transferred, priority of on going collaborative research work changes 7) Collaboration work not discussed at length and at regular intervals 8) Documentation practices, tabulation of results and accuracy of results do not match the standards and requirements of industry 9) The technology developed by academia is not reproducible in the industry premises due to use of incorrect experimental methodologies, use of equipments, facilities, methods and rawmaterials of low standards and quality.

In all the cases it was found that either academia or industry were not satisfied with the collaborative work due to the above mentioned barriers or drawbacks or causes, which damage their relations and hinder all the future collaborations. It was concluded that deficiencies on part of industry and academia lead to barriers, which

can be eliminated by meticulous planning, efficient handling, clear understanding of the concept and modalities of collaboration. Also, the mindset, communication sills and project management skills have to be enhanced to show significant progress in the collaborative research works.

JP 31 Career scenario for pharmaceutics specialization - an analysis

M. Pavan Kumar*, Y. Madhusudan Rao, T. Ashok and K. Chandrasekhar

University College of Pharmaceutical Sciences, Kakatiya University, Warangal

The objective of this paper is to educate the post graduate students opting for pharmaceutics specialization, about the present scenario and the likely changes in the near future for a career in formulation research development (FRD). There has been manifold expansion in the R&D setups and more revenue spending on research has been noticed from Indian pharma companies. This nurtured a great stress on competency of pharmaceutical companies and especially larger ones and also on the skills and competency of postgraduate students. In the last decade, we have seen the different facets of FRD, the days are behind where the formulation scientist used to handle all alone various activities involved in formulating a product right from literature search stage to product launch stage in the market. However, with the advent of modern technologies, specialized excipients, array of equipments, stricter regulatory norms, increase reliance on clinical and bio-studies, marketing products to various international markets has resulted in creation of individual specialized departments.

Investigation of FRD department structure in some of the top pharma companies in India such as Dr.Reddys laboratories, Ranbaxy, Sun pharma, Wockhardt etc has been made investigated. The different specialised functional departments are 1) Solid dosage forms, 2) Liquid and Semi solid dosage forms development 3) Parenteral dosage forms development 4) Novel drug delivery systems 5) Literature survey 6) Preformulation 7) Stability studies 8) Packaging development 9) Pilot /Scale Up 10) Documentation 11) Regulatory affairs 12) Biopharmaceutics and Pharmacokinetics. These specialised departments now handle only a particular activity in the development of new product, unlike in the past under single department i.e., FRD. It was also found that FRD department in some pharma companies such as Sun pharma, Dr Reddys laboratories, and Ranbaxy etc existed separately depending on the country where the developed products are marketed such as 1) FRD department for development of Products intended for domestic markets, 2) FRD for development of products for regulated markets such as USA, EUROPE etc, and 3) FRD for development of products for third world countries and un regulated markets.

The revision of pharmaceutics specialization for post graduate students are on the way such as existence of pharmaceutics, industrial pharmacy, pharmaceutical technology specializations in some indian universities, but not in pace with the job requirement. From the findings and developments, it was concluded that it is the need of the hour for the universities to understand and have a vision in the framing and revision of syllabus. Also for the students opting for core of pharmaceutical sciences i.e., pharmaceutics to introspect and understand the specializations with in, and have a greater edge by more involvement in the area of interest and accordingly orient their project work in the respective specialization. This boasts the potential of students passing out after their post graduation in pharmaceutics specialisation and is competent in the recruitment stage.

JP 32 A focus on software technology in pharmacy

Samanta, M.K., Rohokale Shriram, S.,* Manikandan, S.R., Wesley, N.E.S. and Suresh, B.

Department of Pharmaceutics, J.S.S. College of Pharmacy, Ootacamund, Tamilnadu-643001.

Computer has been used extensively in all areas of science and technology and there seems to be no end in future application. Software is the essential tool through which computer can be used easily. Lot of softwares related to pharmacy field is being made day to day. Areas where softwares applied in pharmacy are Computer Aided Drug Design [CADD] and molecular modeling, biopharmaceutics, formulation development and production technology, computer aided learning and pharmaceutical analysis.

CADD is used to search libraries of molecules, and aids the medicinal chemist in designing the structure that possesses the desired pharmacological properties. Biopharmaceutics involves pharmacokinetics and pharmacodynamics calculations. Softwares used for this purpose are ACSL, ADAPT II, BIOKMOD, BOOMER/MULTI-FORTE, DESIGN, Graph pad prism, NCOMP and NONMEM. Formulation and development involves use of Ruel Induction, Case-Based reasoning, Neural Networks and Genetic Algorithm. Computer simulated pharmacological experiments uses EXPHARM, which are widely applied in practical lessons to help students on giving hand on skills of pharmacological experiments. PCCAL used in teaching and learning materials in pharmaceutical and life sciences which offers an opportunity for students to assess, revise and reinforce their basic knowledge. In conclusion, pharmacist should have knowledge about the computer softwares and its applications. Softwares applications should be emphasized more in undergraduate level. Teachers should motivate students to learn about computer softwares. We should discover from the computer that there is something worthwhile beyond this.

KP$_1$ A study of leprosy cases among general population of Satara District, Maharashtra

S.B.Bhise [1], Niranjan N. Kulkarni [2], Abhijit D. Nalawade [*3]

1. Principal, Govt. College of Pharmacy,Aurangabad.
2. Satara College of Pharmacy, Satara.
3. Govt. College of Pharmacy, Karad-415124.

Leprosy is disease of great antiquity, its origin and early spread, however, largely is a matter of surmise. India accounts for 60.9% of total global recorded cases of leprosy.

A survey was conducted in Satara District Of Maharashtra by collecting information from 71 Primary Health Centres (rural area) and 7 urban Centres.

In this study 1253 patients were identified as having leprosy in Satara District, from March 2002 to March 2003. Out of all registered leprosy patients 18.6%, 58.1% and 41.8% were children, male and female respectively, the values for two types of leprosy were as follows: -Paucibacillary leprosy (62.0%) and Multibacillary leprosy (37.9%).

Paucibacillary is the prominent type of leprosy. Percentage prevalence of both type of leprosy is higher in males.

KP$_2$ Attitudes and awareness concerning tobacco use and its health effects in Pune city, Maharashtra

S.B. Bhise [1], Vikas R. More [2], Abhijit D Nalawade[*3], Hemant Devi [4]

1) Principal, Govt.College of Pharmacy,Aurangabad.
2) Pharmacist, Jehanjir Hospital, Pune.
3) Govt. College of Pharmacy, Karad-415 124.
4) AISSMS College of Pharmacy, Pune.

The present study is aimed at identifying tobacco use and awareness of and attitudes towards tobacco in the adult population of Pune, Maharashtra.

A cross sectional study was conducted in 2003 of a representative sample of 2,874 subjects aged 25 and over. Data was collected by means of a questionnaire. In order to facilitate the analysis of the data a distinction was made between different categories of behaviour such as: - Smokers, ex-smokers, traditional consumers and non- consumers of tobacco.

The overall proportion of ex-smoker was 5.0%, the values for men and women being 10% and 0.1% respectively, i.e. tobacco use was higher in men than women. Current smokers made up 18.3% of the sample. Among men the proportion of current smokers decreased with age. However, for both sexes the proportion of consuming traditional tobacco exclusively increased with age.

Of the individuals surveyed, 98.9% believed that the use of tobacco was damaging to health. Over 90% of the respondents cited tobacco as a factor in the development of cancer, respiratory diseases and heart diseases.

Most tobacco users in Pune were men. Awareness of adverse effects of tobacco use was largely satisfactory, despite certain gaps that could possibly be explained by people's experience of illness and the way they are represented in society.

KP$_3$ Prescription analysis survey for drug consumption in Hingoli District of Maharashtra:-Part II

S.B.Bhise [1], Abhijit D. Nalawade [*2], S. Tarke[2]

1. Principal, Govt.College of Pharmacy,Aurangabad.
2. Govt. College of Pharmacy, Karad-415 124.

Health professionals have a duty to care for their patients. India is a developing country with significant problems related to drug use. Thus, quality of care can be maintained only by practicing rational use by the prescriber and proper checking and handling of prescriptions by the Pharmacist.

In the Part -I (as presented in 54th IPC) of this study, we carried out prescription analysis with reference to World Health Organisation (WHO) guidelines for surveying total Public Health Facilities (PHF's) in a district. It was concluded that, rationality score of Public sector prescription is better than that of Private sector.

The study now been extended to retrospective, Grading of Prescriptions-Education wise Comparison by analyzing them as rational, semi-rational and irrational. For this purpose we had categorized Physician as per their qualifications. Figures of rationality /irrationality for different professionals was as follows: - Consultants (29.2/35.7)%, MBBS (24.1/39.4)%, Non-Allopaths (20.8/46.9)% and RMPs (16.7/49.3)%.

In conclusion, the proportion of rational Prescription has increased with educational qualifications of Physicians. The reverse was true for the proportion of irrational Prescriptions.

KP4 DOTS -based tuberculosis treatment in Satara District, Maharashtra

S.B. Bhise [1], Amol Dhane [2], Abhijit D. Nalawade [*2]

1. Principal, Govt. College of Pharmacy,Aurangabad.
2. Govt. College of Pharmacy, Karad-415124.

Tuberculosis (TB) is an increasingly important cause of mortality in adults than any other infectious disease and has more cases in India than any other country in the world.

The diagnostic and treatment components of DOTS (Directly Observed Treatment, with Short Course) were built on the results of a series of clinical investigations. All protocols in this study were based on guidelines issued by the Indian Revised National Tuberculosis Control Programme (RNTC) and World Health Organisation (WHO). A data from 367 TB centers situated in Satara District of Maharashtra was collected.

In this study 2090 patients were identified as having TB in Satara Disrtict, in year 2002, over 46.2% were smear positive and more than 50% were smear negative and extrapulmonary. Out of all registered TB patients 67.2% and 32.7% were male and female respectively. Among the smear positive patients 83.2% were cured and 3.2% died. Treatment completion rate in smear negative patient was 79.0%.

As compared to earlier years DOTS figures the overall treatment success rate was improved from 70% to 83.2%.

KP5 Total Quality Management

K.S. Patil[1], Rajarajeshwari .N[1*], S.C. Chaturvedi[2]

1) K.L..E.S's College of Pharmacy, Belgaum
2) Shri. G.S.I.T.S. Department of Pharmacy, Indore.

In the context of the liberalisation of Indian economy and increased competition, the Indian industry has adopted the concepts of Total Quality Management to improve the quality of their products and to make them globally competitive. For success in this effort, revitalisation of education and the teaching-learning processes in necessary.

Many of the industries have embraced the concept of Total Quality Management (TQM) and evolved procedures to achieve certification from national and international organizations regarding the assurance of quality in all its facets in their organisation.

Efforts are at present being made to extend the concept of TQM to other sectors like services, education, training etc. An attempt is made in this paper to review the quality systems, as applicable to an industry, and their possible extension to educational institutions.

KP6 "Mobile Pharmacy":- need for improvement in retail pharmacy outlet

N.H. Indurwade, S.B. Kosalge, Ashish Pagariya*, S.S. Chavan, P.B. Suruse, S.V. Uppalwar

S.N. Institute of Pharmacy, Pusad, Distt. Yavatmal (M.S.) Pin - 445 204

Health for all by 2000 A.D. is the motto of international conference on primary health care held in September 1978 at Alma Ata. But this is not achieved until Pharmacy professionals dedicate themselves in the various fields such as research and development; production; academics; marketing; etc. but less importance is given to the proper and efficient distribution of drugs in rural areas.

India's 63% population resides in villages. Among these, 65% resides in villages having population less than 1000 and remaining in villages with population of 1000-4000. The mortality rate in rural areas is very high only due to improper time of medication. This can only be achieved through the establishment of mobile pharmacy. Mobile pharmacy will be well equipped with refrigerator, air conditioners, computer system and mobile phone and other emergency service aids. It can provide services in the rural areas timely and also in emergency conditions. The chronic diseased patients are greater in number in rural areas than the urban one. They require regular and long term drug therapy. This can only be achieved through mobile pharmacy.

Thus mobile pharmacy will be tremendously helpful to treat such diseases in rural area and it can easily achieve our goal, "Health for all".

KP7 Attitude measurement of medical practitioners on the role of goserelin acetate in the management of breast cancer

D. Sreedhar*, K.N. Bopanna[†] and M. Sreenivasa Reddy.

Department of Pharmacy Management, College of Pharmaceutical Sciences, MAHE, Manipal 576 104, Karnataka.

1. Astra Zeneca Pharma India Ltd. Crescent Towers, 32/1-2 Crescent Road, P.O No.5039, Bangalore - 560 001.

Breast Cancer is most common form of cancer among women. Various treatment options are available

viz. Surgery, Radiotherapy, Endocrine therapy and Chemotherapy. Surgery may not be the right choice in perimenopausal women. Radiotherapy and Chemotherapy has some limitations. Goserelin acetate, a leutinizing hormone releasing hormone analog, is indicated in the management of breast cancer. The present study was aimed at finding out the attitude of medical practitioners on the efficacy, evaluating the effectiveness of goserelin against other treatment options and recommending the market strategy.

The study was conducted through a nondisguised structured questionnaire and the primary data was collected through a non probability sampling by convenience method. Oncologists were selected in a specified geographical area. Findings are;

- In early stage and locally advanced breast cancer patients, goserelin acetate was mainly preferred.
- In non invasive breast cancer, surgery followed by radiotherapy was preferred.
- In metastatic breast cancer, physicians said they would try to palliate the symptoms by various treatment options depending on the patient status.

Patient compliance and cost of the therapy was found to be major hindrance for preferring goserelin. More emphasis should be on the strengths of the product such as efficacy, patient convenience and low adverse effects. The following recommendations were made: i).Promotional strategy should be targeted towards building awareness to practitioners, provide samples, value added services and a constant follow-up-day to day progress and ii).The product can be concentrated on other ailments like endometriasis and uterine fibroids also.

KP$_8$ A survey report on silicosis in area of M.P.

Ashawat, M.S[2], Ranawat, M.S.,[1] Chauhan, C.S.[1] Farukh Sheikh

B.N. College of Pharmacy, Udaipur[1], B.N. Girls' College of Pharmacy, Udaipur[2]

The objective of this study was to know the Industrial health problems that are associated with slate pencil industries. These industries not only provide employment to workers but are also responsible for causing one of the most severe occupational disease known as silicosis.

This study was undertaken by considering industrial report and also projecting govt. involvement in dealing with silicosis patients. This project also involves finding out worker's opinion regarding owners support. Both in the areas of economic i.e. employment to worker and health i.e. providing medical facilities to the worker who works in a silicosis prone environment

The project involved a survey based upon a pilot study. The study was conducted by means of questionnaire so design to provide all the necessary information regarding the severity of symptoms of silicosis as well as the diagnostic technique involved. The survey helped us to identity, the various measures to be taken for the prevention of silicosis in accordance Medical measures and factories Act 1976; Mines Act 1952; which require notification of cases of silicosis, maintaining workers health and disability records. The study concluded that the legislative measures by government and preventive measures should be followed strictly by the employer and worker.

KP$_9$ Knowledge and practice of mothers towards treatment of diarrheoa in tribal area

Deokar B.D.*, Kadam S.J., Patil S.B., Mahajan H.S., Wagh R.D.

A. R.A. College of Pharmacy, Nagaon. Dist. Dhule

To assess the knowledge of and practice of mothers regarding treatment and prevention of diarrheoa in tribal area of Dhule district, Maharashtra, India.

A community based cluster study was conducted. A total of 250 mothers were interviewed using questionnaire (prepared in regional language), which include demographic details and questions on treatment and prevention of diarrhoea.

Mean age of mothers 32.98 year.(SD± 6.5). About 35% of mothers were uneducated. Various signs and symptoms were mentioned including loose watery stools (66.68%), frequent stools (56.70%) an vomiting (49.36%) by mothers.

Only 8.90 % of mothers were aware of oral rehydraton solution and 7.56 % exactly knew the method of preparing the same. Only 7.89 % mothers knew the preparation of salt-sugar solution

This study recommends that interventions should be carried out to improve the knowledge and practice of mothers towards the treatment of childhood diarrhoea.

KP$_{10}$ Patient counseling - made easy

Shobha Rani. R. H[1], Praveen. S[1], Hamant Kumar[2]* and Sanjay Upadhyay[2]

1. Al-Ameen College of Pharmacy, Hosur Road, Bangalore - 560 027.

2. The Oxford College of Pharmacy, J.P. Nagar, Bangalore - 560 078.

The importance of patient counseling has come to the forefront in India today. This may be due to the practice of poly pharmacy in several co-morbid conditions leading to the precipitation of adverse drug reactions, drug interactions and non-adherence to dosage regimen. Patient counselling not only helps in educating the patient about his medications, but also serves to open communication lines between the pharmacist and the patient. This would allow the pharmacist to give better health care as he/she would be better informed of the patient's overall health and could further help the patient in leading a healthier life. A questionnaire-based survey on the perspectives of "Community Pharmacy" by practicing Community Pharmacists was conducted across Bangalore - South. (The results of which were presented at the 54th IPC held at Pune in 2002.) As per the survey, many of the Community Pharmacists' felt the need of specific guidelines and literature to carry out patient counseling. In view of this, the present work was taken up, which aims at developing a user-friendly database, which gives the pharmacist the 'Patient Counseling' information for each pharmacological class of drugs. The database is created in 'MS-Access' and can be run on Windows operating system. Since MS-Access is available in the MS-Office suite, it can be used on any computer, thus making it economical and user-friendly.

KP11 A prospective review and survey with marketing executives on pharmaceutical marketing

Mohamed Reyas.M*, Madhusudhan.S, Dhanapal.C.K, Manna.P.K. and Manavalan.R

Institute of Pharmaceutical Technology, Annamalai University, Annamalai nagar, Tamil Nadu - 608 002

The present investigation was carried out with the objective to interact with Marketing executives and to collect profiles of the company, product and personals involved, marketing strategies followed, their suggestions, opinions etc on various aspects, including promotional aids, HRD and Motivation factors, etc. A Questionnaire (Survey form) was prepared for field study and formal personal interview were carried out with twenty field sales executives drawn across Tamil Nadu. From the field survey it was observed that Representatives visit around 55 to 120 doctors per month and around 10 to 12 doctors/day and about 5 to 8 pharmacies/ day.

Few attributes that are important for marketing, as suggested by field staff are listed based on the order of priority are as follows: (1) Product performance (2) Brand loyalty (3) Company Reputation (4) Approach of Medical representatives (5) Literature about product, (6) Price of the product, (7) Physician Samples (to Doctors & Pharmacy), (8) Price discount, margin, commission, dealings etc. On personnel interrogation, it was found that price discount and dealing with retailers and doctors assumes significant role to achieve sales target. The remuneration to the field staff varies greatly from firm to firm and between designations. Salary for the Medical representatives ranges from Rs. 2,500/ p.m. to Rs. 5,000/ p.m.

We look forward that in post GATT era, Pharmaceutical companies will follow ethical method of promotion and give more importance to TQM, GMP etc. and follow better marketing strategies.

KP12 Are we ready for community pharmacy in India? - A case study

Krutika K. Sawant*, Vijay J. Ahire, Neetu Y. Sheth

Pharmacy Dept., The M.S. University of Baroda, Vadodara - 390001 (Gujarat)

Community Pharmacist is a vital link in the health care services. Community Pharmacy in India is still in nascent stage and is confined to the so-called `medical store'. The community pharmacy as a concept is not clear in India and is confused with the job of selling the drugs at a retail counter. Our community pharmacist has yet to start the actual practice of dispensing the prescription and patient counseling as practiced in developed countries. The present study was conducted to judge whether we are ready to adopt the community pharmacy model in India? What is the status of the retail counters? The status was evaluated with respect to three main areas:

A. Pharmacy and Pharmacist; B. Prescription Handling; C. Patient Counselling D. Miscellaneous. The survey was carried out in Vadodara using a questionnaire. All the answers were graded from -2 o +2. Depending on these points the pharmacies were divided into four groups with following results: 1. Excellent 0 (0%); 2. Very Good: 6 (11%); 3. Good: 24 (43%); 4. Poor: 26 (46%). Only 15% of the pharmacists were B. Pharm. graduates and those pharmacies were in the Good-V.Good range and were also implementing GPP. Most pharmacies could score 20-40% in prescription handling section while the average score was just 2% in the patient counseling section. The Pharmacy section (A) is well equipped in terms of storage and other facilities, earning maximum points, but when it comes to prescription handling section (B) and patient counseling section (C) they just dispense the drugs against prescriptions, no heed is given to special input in contraindicated drugs, wrong prescriptions, rationale drug selection & substitution and patient counseling, earning negative points. Many pharmacists accepted that they had not been able to fulfill the challenging role of community pharmacy and most of them sought self-improvement to provide better services to the patients. Thus, this survey exposes the pathetic state of community pharmacy in Vadodara. And

if this is the situation in urban, well developed city, the plight of the community in rural areas just remains to be imagined! Some suggestions to improve the present state of affairs are given:-

- Extensive Training in the proper use of and detailed profile of the drugs.
- The present medical store should be totally converted into professional community pharmacy centre by giving proper training to the Pharmacist.
- Implementation of dress code, identity card, Good Pharmacy Practice should be made compulsory.
- A standard remuneration should be provided to the pharmacist so that highly qualified personnel will take interest in community pharmacy as a career.
- Model Community pharmacies should be started at districts and taluka places.
- Successful completion of orientation program should be a pre-requisite for renewal of registrations.

KP 13 Corporatisation of community pharmacies in India; growth prospects and problems

***Pankaj Agrawal;** Seema Agrawal**

* GGSIP University, Kashmere Gate, Delhi.

** Mill. Health Care Society of India.

The application of corporatisation of community pharmacies in India entail as the exploration of future changes in the environment in which the business operates, so that it may be prepared to adapt as necessary to remain successful.

Through various studies, it has been observed that though the infrastructure is in place in most areas, they are grossly underutilized because of poor facilities, inadequate supplies, insufficient effective person-hours, poor managerial skills of pharmacists. Faulty planning and lack of proper monitoring and evaluatory mechanisms. Further the system being based on the pharmacist/ assistants team concept failed to work because of the mismatch of training and the work allocated to pharmacists and assistants, inadequate transport facilities, non availability of appropriate accommodation for the team and unbalanced distribution of work and time for various activities.

To overcome these discrepancies and outcomes, the corporate community pharmacies sectors need to be introduced in the health care system. This system will meet the demands of the masses, especially residing in the rural vicinities and assures the equity and universal coverage.

The methodology for the design, selection of strategies, and implementation of corporatisation of community pharmacies are: listing each task to be performed, estimate time required for its completion; Identification of the physical output at the completion of each step, such as interview notes, flow charts, management system etc; Cost savings by reducing staff or improving productivity; Integration of computers, robotics and telecommunication technology can enhance the corporatisation of community pharmacies.

Today, we are at the threshold of another transition, which will probably bring about some of the changes like regulations, price control, quality assurance, rationality in community pharmacy practice etc.... this is the coming of the private health insurance that will lay rules of the game for providers to suit its own for-profit motives, while this may improve quality and accountability to some extent. While corporatisation of the community pharmacies sector will take its own time, certain positive changes are possible within the existing setup through macro-policy initiatives.

KP 14 A look over various brands of herbal antidiabetic drugs

Chauk D.S.*, Deokar B.D., Kadam S.J., Patil P.N., Patil S.B., Mahajan H.S., Wagh R.D.

A.R.A.College Of Pharmacy, Dist. Dhule.

To find different herbal anti-diabetics available either signally or in combination and the number of brands available of each.

The survey to find herbal antidiabetics of different generic classes and different brand names of one compound. About 100 brands were viewed.

The brands containing single drug were only few like, GREENEEM◊ Capsule, (extract of Neem leaves), JAMBUKALP◊ (Jambutwak), JAMBUBEEJ◊ choorn / tablet (Jamubeej), NEEMOL◊ Capsule (Neembark) KARELA GHANVATI◊ (Karela Ghan), MAMEJAVA◊ GHANVATI◊ (Mamejawa Ghan), ANTIDIABETIC CAPSULE◊ (Cichorir Root) etc. The numbers of brands were studied which consist of two or more herbal antidiabetic drugs in combination. The combinations of drugs in a single formulation present were upto maximum of 33. It was also observed that the same manufacturer has formulated number of brands containing different herbal antidiabetic drugs. Shri Baidyanath Bhavan, Nagpur. have manufactured 16 brands of different herbal antidiabetics.

From this study it is clear that, there is increase in demand of herbal antidiabetics for the treatment of diabetes mellitus. Hence the most of the industries and physicians are concentrating on herbal antidiabetics.

KP15 A survey on the prevalance of various diseases and the factors affecting them In the capital of Jharkhand

Avijit Mazumder*[1], Rupa Mazumder[1], S.P. Basu[2]

1. Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi - 835 215, India
2. Seemanta Institute of Pharmaceutical Sciences, Jharpokara, Mayurbhanj - 757 087, India

All pharmaceutical houses should have a thorough knowledge about the occurrence of different diseases in different parts of the country in order to strengthen their R and D as well as to gear up their marketing tools in the competitive global market. A survey was conducted in different clinics and hospitals including RMCH and Appollo at Ranchi where 506 patients and 62 physicians were surveyed to have an idea of prevalence of different major diseases and their causes. Asthma, diabetes, hypertension and different infectious diseases were found to be the top four major diseases. Majority of the urban populations particularly males in the age group of 5 to 18 years are suffering from asthma. This may be due to environmental pollution in the cities. Diabetes and hypertension are also found to be very prevalent among urban people, particularly in the age group of 30 to 50 years and 18 to 30 years respectively. The major reason as attributed by the physicians includes food habit and stress of modern life. On the contrary, rural populations were very much susceptible to bacterial and viral infections than urban population. Tuberculosis, leprosy, coughs and cold, pneumonia and polio are some of the major infectious diseases of the tribals whereas incidence of individuals suffering from cough and cold was more in urban locality. 25% of the tribal children belonging to the age group up to 5 years are suffering from infections. 85% of the tribal populations surveyed depends on traditional remedies for the cure of different diseases and very rarely seek the opinion of physicians to cure different diseases. Ignorance, poverty, self-medication and poor hygienic and sanitary conditions of the villages are some of the reasons for the spread of the infectious diseases in the rural area.

KP16 Control of antimicrobial resistance crisis: role of house wives

N.H. Indurwade; S.B. Kosalge; V.V. Redasani; S.S. Chavan*.

Sudhakarrao Naik institute of pharmacy, Pusad-445 204. Dist-Yavatmal. (M.S.)

Disease-causing microbes that have become resistant to drug therapy are an increasing public health problem. Tuberculosis, gonorrhea, malaria, and childhood ear infections are just a few of the diseases that have become hard to treat with antibiotic drugs. Unless antibiotic resistance problems are detected as they emerge, and actions are taken to contain them, the world could be faced with previously treatable diseases that have again become untreatable, as in the days before antibiotics were developed.

Housewives are the group of mature women caring the family in health and illness. They know the common illness and some medicine of treatment for it. They do trials also but are not confident about cure. They frequently visit doctors for themselves and for their family members and get the prescription of antibiotics. During treatment they may face other problems of health, which may be the side effects of improper use of antibiotics. These side effects are not part of disease but the patients feel the same. If this group is properly trained or educated about the drugs, improper use of drugs can be minimized and administration of drugs may be done correctly.

KP17 Making a career as a pharmaceutical sales representative - prospects and pitfalls

Jay Visaria*, Manjiri Gharat, S. S. Poddar

K.M. Kundnani College of Pharmacy, 47-R.G. Thadani Marg, Worli Sea-Face, Mumbai 400 018

The pharmaceutical sales representative plays a vital role in directly informing & influencing a prescriber favorably towards his company's products and enhancing its image.

To evaluate pharma sales career in the view of those pharmacy graduates who are already in the profession and to inform potential entrants regarding a career in sales.

A close-ended questionnaire was circulated among working sales representatives (n=50) in Mumbai and the responses were collected personally and analyzed.

- 88% respondents had chosen a career in pharma sales and 12% had accepted the career due to lack of better alternatives
- Over 90% respondents felt their contribution to the company's sales was highly significant.
- 60% respondents felt the claims they made for the company's products were justified and quality of the products was good while 24% said some product claims were exaggerated.
- 26% respondents said they would opt for further studies in the future.
- Major grievances about the job were poor scope for promotion (20%), low pay (16%) and availability of

other job opportunities (18%), job related stress and unrealistic sales targets (20%).

- Nearly 75% respondents felt pharmacy know-how was essential for their work.
- Appearance, personality and presentation skills were found to be of paramount importance in the field.

Pharmaceutical sales is a feasible career option for undergraduates and today's sales force is well equipped to meet current and future professional challenges. Addressing their grievances could further improve their productivity.

KP 18 Specialisation In B.Pharma. : The need of New Era

N.H. Indurwade, S.B. Kosalge, V.V. Redasani M.R. Chhajed*

S.N.Institute of Pharmacy ,Pusad (M.S.)

The pharmacist of tomorrow need a better identity .He should not only a part of industry but also efficient member of the health care system and so with courage, commitment and compassion. The pharmacist of own better identity shall take birth now.

In present condition the pharmacist has no social status and much important day by day the newer technology are developing and comparatively the pharmaceutical education is not upgraded up to a level. So there should be modification in pharmaceutical education to bring the integrity of education through the country for developing future pharmacists steps should be taken or strengthening or improving the basic organisation of pharma.

KP 19 cGMP regulations for medical devices

Milind J.Bhitre*, Deepali D. Mohite, Aparna R.Patil

C. U. Shah College of Pharmacy, S N D T Womens University, Jubum Santacruz (W), Mumbai 400 049

CGMP regulations are the important part of all pharmaceutical industries. It was mandatory for pharmaceutical industries, which involve in manufacturing of drugs, to follow GMP rules upto 1980s. But the medical devices which are in direct contact with patient and can cause serious life threatening effects on human life, if not safe, were out of focus of GMP rules.Goverment Accounting Office (GAO) in 1980, found that 40% of quality problems were due to errors or deficiencies in medical device design and decided to revise GMP for medical devices.

The aim of our paper is to focus on the different regulations put forth by FDA in cGMP for medical devices. Rules are described in section 820. We have described different subparts of section 820.

Subpart A includes different provisions of manufacturing of medical devices. Subpart B describes quality system regulations followed by manufacturers. Subpart C describes about design control. Subpart D describes documentation controls. Subpart E deals with purchasing control. Subpart F is about identification and traceability and is important to avoid mix-ups of products. Subpart G deals with production and process controls. Further subpart H, I, J, K, L, M, N, and O describes about acceptance activities, nonconforming product, corrective and preventive actions, labeling and packaging control, handling, storage and distribution, record keeping, servicing and statistical techniques respectively.

Thus the paper work has focused on need of different regulations that are to be followed by manufacturing industries and briefly described the rules and regulations mentioned in cGMP for medical devices.

KP 20 How pictograms can reinforce patient information

Manmeet Kaur*, Manas Jyoti Bharadwaj, Raman Dang

Al-ameen College of Pharmacy, Hosur Road, Near Lal Bagh Main Gate, Bangalore 560 027

The well designed pictograms are simple, clear, graphic symbols able to convey their intended meaning to all patients, including those who are illiterate, elderly or visually impaired. However, the success of pictograms as a communication aid in pharmacy depends first on a rigorous design process, followed by well designed, randomised, controlled trials using an appropriate method of evaluation. With pictograms there is an opportunity of automatic replacement of words in pictures for better understanding text. It will also allow to sense the text quickly and so increases the speed of information exchange in case or emergency.

Extensive study was done towards their design, practice, reasons for their use in pharmacy and their potential in improving medication compliance. It is a first report on the new created labels using the already approved pictograms which are on trial basis. The positive and negative aspects of various pictograms were critically evaluated.

KP 21

Quality Management : Ground level facts

Anjali I*, Zaina P.Q., Poddar S.S.

K.M. Kundnani College of Pharmacy, 47, R.G. Thadani Mar, Worli Seaface, Mumbai - 18.

Total quality management is an integral part of the pharmaceutical profession. But with the effort and finances required to ensure TQM, it is being neglected. Thus the objective of our study was to find out to what extent TQM was being implemented in pharmaceutical companies and to assess the possibility of their success as a result of TQM.

In lieu of the above a model survey was conducted and responses poured in were quantified and analyzed using suitable statistical techniques. 10 pharmaceutical companies were shortlisted as representatives of 3 categories : Indian Majors / MNCs, Indian Non-majors and Foreign MNCs. The respondents included: Production dept, R&D dept, Quality control dept, Managers, Doctors and Patients. 75% of production dept said that constant checks on them were detrimental to smooth functioning. 20% expressed their approval of TQM. 20% of R&D dept said they were already overburdened without TQM to add to their workload. 60% of company heads thought it was impossible to keep personal check on eveyrthing. 90% confessed that TQM was not being practiced efficiently. 75% of doctors claimed no improvement in quality of drugs in the past 10 yrs. 95% of patients said that medicines were becoming unaffordable due to the claims on quality improvement made by companies.

The experiment was thus successful in highlighting the following :

1. Customer mainly patient satisfaction was not considered a deciding factor by pharmaceutical companies.
2. 8 out of 10 companies raise cost of drugs without an associated rise in quality
3. Business process outsourcing was another aspect of the moeny saving strategy where authenticity of the processes used outside was not assessed.
4. Statistical quality control from the raw material stage at frequent intervals was considered time consuming and caused reduction in inventory.
5. Many employees stated that TQM was the reason behind reduction in productivity and increase in wastage.

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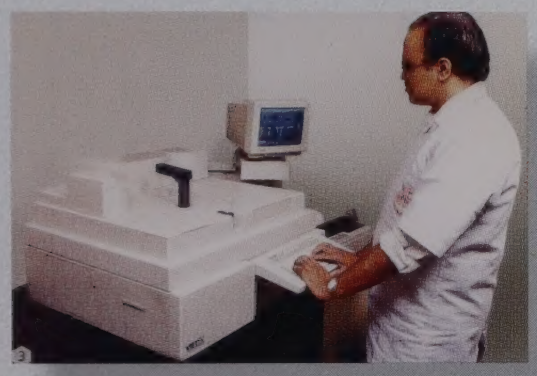

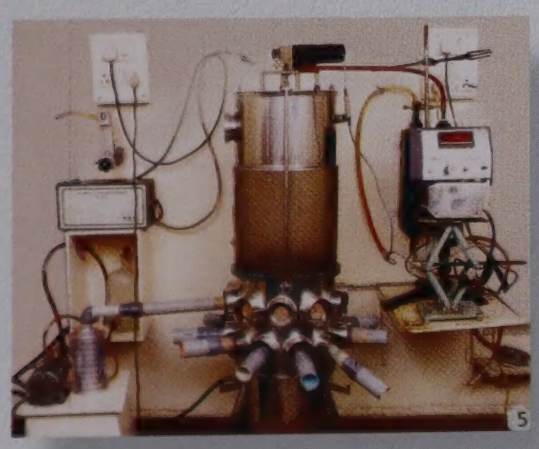

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Other protocol Specific Studies

Subchronic Toxicity

Intubation Toxicity
Dietary Toxicity
Dermal Toxicity
Inhalation Toxicity
Intravenous Toxicity
Intraperitoneal Toxicity
Intramuscular Toxicity
Subcutaneous Toxicity &
Other protocol Specific Studies

Neurotoxicity

Reproductive Toxicity

Teratogenicity
Generation Studies

Chronic Toxicity

One Year Dietary
Carcinogenicity

Ecotoxicity

Toxicity to
Birds
Fish
Beneficial Insects
Daphnia
Alga
Earthworm etc.

Species Maintained

Mice
Rat
Rabbit
Guinea Pig

Genetic Toxicology

Salmonella Reverse Mutation Assay (Ames Test)
In-vivo-Micronucleus Test
Chromosomal Aberrations
Dominant Lethal Test
In-vitro-ChromosomalAberrations

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Centre of Relevance and Excellence in Herbal Drugs, Supported by DST, New Delhi.

CADRAT - Centre for Advanced Drug Research And Testing

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